US3142161 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142161
Form: Participant Creation
Data signed: (b) (4) **18 Apr 2021 20:29:30**
Generated On: 09 Jun 2021 15:27:33

Participant ID   US3142161

mRNA-1273-P301 Completion Guidelines

US3142161

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	08 AUG 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) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Date of Informed Consent *(dd MMM yyyy)*	08 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Did the participant meet all eligibility criteria?   Yes ●

No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Were any significant conditions reported?   Yes ●

                                                     No ○

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Folder: Screening

Form: Medical History (1)

Data signed: [(b) (4)] **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	POSTNASAL DRIP
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3142161

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1952
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1952
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1952
Start Year (derived)	1952
Stop Month and Year (derived)	JAN 1952
Stop Year (derived)	1952

US3142161

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3142161

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	OA
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)	

US3142161

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3142161

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	8 AUG 2020
Time of assessment *(00:00-23:59)*	09:51 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 09:51
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	183 lb
BMI *(xxx.x)*	32.48478 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)	

US3142161

Folder: Screening

Form: Physical Examination

Data signed: (b) (4)   **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

| Was the physical examination performed? | Yes ● |
| | No ○ |

Date of examination *(dd MMM yyyy)*   8 AUG 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) ▨ **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*	8 AUG 2020
Is the participant of childbearing potential?	Yes ◯
	No ⬤

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

If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 2002
Date of last menstruation unknown	False

US3142161

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **18 Apr 2021 20:29:31**

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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) **18 Apr 2021 20:29:31**

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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)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	8 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●

Folder OID	VISIT1

US3142161
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **18 Apr 2021 20:29:31**
Generated On: 09 Jun 2021 15:27:33

What was the date of randomization? *(dd MMM yyyy)*	08 AUG 2020
What was the participant's randomization number?	185300

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 ⬤

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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)*	8 AUG 2020
Time of assessment *(00:00-23:59)*	09:51 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 09:51
Temperature *(xxx.x)*	98 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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)*	8 AUG 2020
Time of assessment *(00:00-23:59)*	10:52 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:52
Temperature *(xxx.x)*	99.2 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **18 Apr 2021 20:29:31**
Generated On: 09 Jun 2021 15:27:33

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)*	08 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:22 (24 HR)
Treatment Date and Time (derived)	08 AUG 2020 10:22

Which arm was used to give treatment?   Left Arm ●

                                                         Right Arm ○

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4)   **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?	Yes ⬤
	No ⭕
Collection date *(dd MMM yyyy)*	8 AUG 2020
Collection time *(00:00-23:59)*	09:58 (24 HR)
Collection date and time (derived)	8 AUG 2020 09:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*   8 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:58	8 AUG 2020 09:58
Nasopharyngeal Swab 2	Yes	09:58	8 AUG 2020 09:58

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ / No ●

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

PC Time Stamp	08 AUG 2020 10:57
PC Open Date & Time	08 AUG 2020 10:42
PC Close Date & Time	08 AUG 2020 13:12

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**	98.0 °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	09 AUG 2020 09:25
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0092122

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

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**	98.0 °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	09 AUG 2020 16:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	10 AUG 2020 14:21
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	11 AUG 2020 12:01
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes	⬤
	No	◯
Please record your **TEMPERATURE in °F**		98.7 °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	12 AUG 2020 13:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

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**	97.5 °F

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

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

PC Time Stamp	13 AUG 2020 12:30
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 AUG 2020 12:05
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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	08 AUG 2020 10:58
PC Open Date & Time	08 AUG 2020 10:42
PC Close Date & Time	08 AUG 2020 13:12

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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 ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	4
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	09 AUG 2020 09:26
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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 ◯

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	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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	10 AUG 2020 14:22
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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	11 AUG 2020 12:02
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	12 AUG 2020 13:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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	13 AUG 2020 12:30
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33

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

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

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 ○

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	08 AUG 2020 10:59
PC Open Date & Time	08 AUG 2020 10:42
PC Close Date & Time	08 AUG 2020 13:12

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33

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 ○

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

No ⬤

Yes ◯

PC Time stamp	09 AUG 2020 09:27
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33

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	09 AUG 2020 16:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33

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 ●

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

	Yes ◯
PC Time stamp	10 AUG 2020 14:22
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33

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	11 AUG 2020 12:02
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33

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 〇
PC Time stamp	12 AUG 2020 13:42
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

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	13 AUG 2020 12:31
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

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

US3142161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3142161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3142161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	31 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3142161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)　**18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	9 SEP 2020
Time of assessment *(00:00-23:59)*	15:30 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 15:30
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Timepoint	Pre-Dose ⚪
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⚪
Date of assessment *(dd MMM yyyy)*	9 SEP 2020
Time of assessment *(00:00-23:59)*	16:22 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 16:22
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ⚪
	Axillary ⚪
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3142161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

| Was the physical examination performed? | Yes ⬤ |
| | No ◯ |

Date of examination *(dd MMM yyyy)*   9 SEP 2020

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

Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **18 Apr 2021 20:29:31**
Generated On: 09 Jun 2021 15:27:33

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)*	9 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:52 (24 HR)
Treatment Date and Time (derived)	9 SEP 2020 15:52
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

US3142161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

| Was the sample collected? | Yes ● |
| | No ○ |

Collection date *(dd MMM yyyy)*	9 SEP 2020
Collection time *(00:00-23:59)*	15:34 (24 HR)
Collection date and time (derived)	9 SEP 2020 15:34

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)* 9 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	9 SEP 2020 15:30
Nasopharyngeal Swab 2	Yes	15:30	9 SEP 2020 15:30

US3142161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	98.3 °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	09 SEP 2020 16:24
PC Open Date & Time	09 SEP 2020 16:12
PC Close Date & Time	09 SEP 2020 18:42

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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**	98.3 °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	10 SEP 2020 09:06
PC Open Date & Time	09 SEP 2020 19:37
PC Close Date & Time	10 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.1 °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	11 SEP 2020 09:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	12 SEP 2020 09:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.5 °F

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

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

PC Time Stamp	13 SEP 2020 09:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

| Please record your **TEMPERATURE in °F** | 98.3 °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	14 SEP 2020 08:18
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

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**	97.5 °F

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

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

PC Time Stamp	15 SEP 2020 05:19
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:27:33

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	16 SEP 2020 10:09
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

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	09 SEP 2020 16:18
PC Open Date & Time	09 SEP 2020 16:12
PC Close Date & Time	09 SEP 2020 18:42

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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	10 SEP 2020 09:07
PC Open Date & Time	09 SEP 2020 19:37
PC Close Date & Time	10 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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	11 SEP 2020 09:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33

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	12 SEP 2020 09:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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	13 SEP 2020 09:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	14 SEP 2020 08:18
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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	15 SEP 2020 05:19
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

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	16 SEP 2020 10:10
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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 ◯

FDA-CBER-2022-1614-0092183

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	09 SEP 2020 16:18
PC Open Date & Time	09 SEP 2020 16:12
PC Close Date & Time	09 SEP 2020 18:42

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33

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 ○

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	10 SEP 2020 09:07
PC Open Date & Time	09 SEP 2020 19:37
PC Close Date & Time	10 SEP 2020 11:59

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

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	11 SEP 2020 09:59
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0092188

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33

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	12 SEP 2020 09:40
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33

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	13 SEP 2020 09:37
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33

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	14 SEP 2020 08:19
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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 ●

FDA-CBER-2022-1614-0092195

	Yes ◯
PC Time stamp	15 SEP 2020 05:20
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0092196

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33

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	16 SEP 2020 10:10
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3142161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 15 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments _____

US3142161

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3142161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 22 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

                                                                                                        No ○

Continuing Flag   1

US3142161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3142161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT3

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	22 OCT 2020
Time of assessment *(00:00-23:59)*	15:10 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 15:10
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?   Yes ●

          No ○

Date of examination *(dd MMM yyyy)*   22 OCT 2020

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

US3142161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	22 OCT 2020
Collection time *(00:00-23:59)*	15:37 (24 HR)
Collection date and time (derived)	22 OCT 2020 15:37

US3142161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 12:00:57
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 00:08:26
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 12:07:36
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 00:01:57
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 13:34:54
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 106

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ⬭

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 00:02:02
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 12:01:17
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 00:02:06
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 04:22:35
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ●
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have 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):	
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 ●
Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 DEC 2020 12:01:11
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 06:46:15
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 15:24:52
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 12:13:00
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 00:02:07
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 11:59:25
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT   **DAY 180**

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

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 187

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

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

Fever (Temperature ≥ 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 ⃝

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT   DAY 194

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

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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-2022-1614-0092233

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3142161

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:27:33

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

US3142161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○
Comments	FLU SHOT 20OCT2020

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3142161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 4 DEC 2020 |

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

Comments

If Contact Not Made, please provide Comments

SUBJECT HAS STARTED ELIQUIS 5MG 2X DAY FOR STROKE. SUBJECT WAS IN ER FOR 24HRS ON 23NOV2020

US3142161

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3142161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3142161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3142161

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3142161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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　　　　　　　　　　　　　　　　　　　　　　　VISIT4

US3142161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

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)	_____

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 the sample collected?   Yes ◯
                                                              No ◯

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

Is the participant continuing to the next visit?   Yes ⭕

No ⭕

Continuing Flag

US3142161
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:27:33

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 ◯

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

US3142161

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

Form: Visit Date

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3142161

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

Form: Unblinding

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Date of updated informed consent *(dd MMM yyyy)*	24 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	24 FEB 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	1
Continuing with mRNA-1273	

Was the sample collected?   Yes ◯

                                                                                No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3142161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?   Yes ◯

                                                             No ⬤

Collection date *(dd MMM yyyy)*

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

Collection Date and Time (derived)

US3142161

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **18 Apr 2021 20:29:30**

Generated On: 09 Jun 2021 15:27:33

Did the participant experience any adverse events?   Yes ●

                                                           No ◯

If Yes, enter details on the Adverse Events form.

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **18 Apr 2021 20:29:30**

Generated On: 09 Jun 2021 15:27:33

AEID	USA-US064-2021-MRNA-1273-P30 1000006
Adverse event	STROKE
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)*	23 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	23 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ●
	No ○
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	23 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	24 NOV 2020
Admitted to ICU?	Yes ○
	No ●
	Unknown ○

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **18 Apr 2021 20:29:30**

Generated On: 09 Jun 2021 15:27:33

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	True
Concomitant Medication	False
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD A STROKE 23NOV2020. HOSPITALIZED FOR 24 HOURS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

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

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4)   **26 Apr 2021 02:42:10**
Generated On: 09 Jun 2021 15:27:33

Name of Medication	ASPIRIN

Prophylaxis   Yes ●
             No ○

Indication	GENERAL HEART HEALTH
Dose per administration	81

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 UNK 2013
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 (2)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	LOSARTAN
Prophylaxis	Yes ◯
	No ⬤
Indication	HYPERTENSION
Dose per administration	50
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

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 2013
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-2022-1614-0092262

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: [(b) (4)] **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	PRAVASTATIN

Prophylaxis	Yes ⚪
	No ⚫

Indication	HIGH CHOLESTEROL

Dose per administration	40

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 UNK 2007
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	ZYRTEC
Prophylaxis	Yes ⬭
	No ⬤
Indication	SEASONAL ALLERGIES
Dose per administration	10

Dose unit	
	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration	
	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭
	Intraocular ⬭

	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 2010
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-2022-1614-0092266

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	SYMBICORT
Prophylaxis	Yes ⚪
	No ⚫

Indication	ASTHMA
Dose per administration	2

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 UNK 2002
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)	2
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 (6)

Data signed: (b) (4)   **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	ALBUTEROL

Prophylaxis

Yes ◯
No ⬤

Indication	ASTHMA
Dose per administration	2

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)*	UN UNK 2002
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 (7)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	FLU VACCINE

Prophylaxis	Yes ●
	No ○

Indication	FLU PREVENTION
Dose per administration	UNKNOWN

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

If dose unit is Other, specify	UNKNOWN

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)*	20 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	20 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 ○

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

Name of Medication	ELIQUIS

Prophylaxis	Yes ●
	No ○

Indication	STROKE PREVENTION

Dose per administration	5

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

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 NOV 2020
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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3142161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Were any concomitant procedures performed?   Yes ◯

                                                                              No ⬤

If yes, please complete Concomitant Procedures form.

Date of dosing discontinuation (dd MMM yyyy) _____

Primary reason for dosing discontinuation

AE (specify) ◯
SAE (specify) ◯
Death ◯
Lost To Follow-up ◯
Physician decision (specify) ◯
Pregnancy ◯
Protocol deviation (specify) ◯
Study Terminated By Sponsor ◯
Withdrawal of consent by
participant (specify) ◯
Due to SARS-COV-2 ◯
Other ◯

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

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) **18 Apr 2021 20:29:31**

Generated On: 09 Jun 2021 15:27:33

Date of study discontinuation/completion *(dd MMM yyyy)*	24 FEB 2021

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	SUBJECT RECEIVED OUTSIDE MODERNA VACCINE AND WITHDREW CONSENT AT UNBLINDING VISIT.

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 ◯

SAEID	USA-US064-2021-MRNA-1273-P30 1000006
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US064-2021-MRNA-1273-P30 1000006
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/JAN/2021 09:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: ▨ (b) (4) ▨ **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US064-2021-MRNA-1273-P30 1000006
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: ▮(b) (4)▮ **26 Apr 2021 02:42:10**

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US064-2021-MRNA-1273-P30 1000006
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142161 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142161
Form: Participant Creation
Generated On: 09 Jun 2021 15:27:33
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:33:51
User entered 'US3142161'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 15:35:34

US3142161
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:46:55
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:58:34

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US3142161

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:46:56
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 15:35:35

US3142161

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:46:58
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:58:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'SCRN'	System	10 Aug 2020 19:58:34

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:47:18
User entered '(b) (6)1948'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 15:35:36

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:21
User entered '72'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'YEARS'	System	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '72'	System	08 Aug 2020 16:33:34

US3142161

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:22
User entered 'Female (F)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:32
User entered '1'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:35
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

FDA-CBER-2022-1614-0092296

US3142161

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

US3142161
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:27:33
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:39
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:13

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered '08 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Aug 2020'	System	08 Aug 2020 16:33:34

FDA-CBER-2022-1614-0092304

US3142161

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2020'	System	08 Aug 2020 16:33:34

US3142161
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:27:33
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User closed query 'Please reconcile Amendment Version number with SD' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:16:04
DataPoint Verified.		07 Jan 2021 17:16:00
Query 'Please reconcile Amendment Version number with SD' answered with 'corrected ' (Site from CRA).	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:46:02
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:45:53
User opened query 'Please reconcile Amendment Version number with SD' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 22:12:09
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	09 Dec 2020 23:24:52
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	09 Dec 2020 23:24:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered 'Amendment 1 (1)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

US3142161
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:27:33

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

US3142161

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

US3142161

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

US3142161
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:27:33

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:34

US3142161
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:27:33
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:47:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 15:35:35

US3142161

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1'	System	08 Aug 2020 16:33:41

US3142161

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:27:33

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:06
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:33:41

US3142161

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:27:33

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:54:20
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 19:59:32

US3142161
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:27:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User closed query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.' (Site from DM).		15 Oct 2020 04:22:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:42:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:42:32
Data point term sent to Coder	System	14 Oct 2020 16:41:49
Query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:41:43
Coding entries removed.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:41:34
User entered 'bilateral CATARACTS' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:41:34
User opened query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 11:51:37
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:30:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:30:29
Data point term sent to Coder	System	10 Aug 2020 20:00:47
User entered 'cataracts'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2010'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User closed query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).		15 Oct 2020 13:38:30
Query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' answered with 'subject had cataracts removed ' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:42:01
User opened query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 11:52:00
User entered 'UN UNK 2010'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2010'	System	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2010'	System	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2010'	System	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2010'	System	10 Aug 2020 20:00:27

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
Data point term sent to Coder	System	10 Aug 2020 20:01:53
User entered 'postnasal drip'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2010'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2010'	System	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2010'	System	10 Aug 2020 20:00:58

US3142161
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:00:58

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:01
Data point term sent to Coder	System	10 Aug 2020 20:01:53
User entered 'seasonal allergies'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2010'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:01:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2010'	System	10 Aug 2020 20:01:26

FDA-CBER-2022-1614-0092341

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2010'	System	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:01:26

US3142161

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:01:26

US3142161
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:27:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
Data point term sent to Coder	System	10 Aug 2020 20:02:58
User entered 'tonsillitis'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 1952'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 1952'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 1952'	System	10 Aug 2020 20:02:13

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US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1952'	System	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 1952'	System	10 Aug 2020 20:02:13

US3142161

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1952'	System	10 Aug 2020 20:02:13

US3142161
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:27:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).		15 Oct 2020 03:40:48
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'ConMed page is now updated ' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:44:07
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 11:52:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:41
Data point term sent to Coder	System	10 Aug 2020 20:02:59
User entered 'asthma'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2002'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2002'	System	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2002'	System	10 Aug 2020 20:02:40

US3142161

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:02:40

US3142161
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:02:40

US3142161
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:27:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Bleeding tendencies, PT: Increased tendency to bruise, LLT: Tendency to bruise easily - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:41
Data point term sent to Coder	System	10 Aug 2020 20:04:00
User entered 'bruise easily'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2013'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2013'	System	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2013'	System	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:03:41

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:03
Data point term sent to Coder	System	10 Aug 2020 20:05:02
User entered 'hypercholesterolemia'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2007'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2007'	System	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2007'	System	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:04:33

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:47:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:47:29
Data point term sent to Coder	System	10 Aug 2020 20:05:03
User entered 'OA'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2005'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

FDA-CBER-2022-1614-0092386

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2005'	System	10 Aug 2020 20:05:01

US3142161
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:27:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2005'	System	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:05:01

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
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)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	10 Aug 2020 20:06:07
User entered 'post menopausal'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2002'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

FDA-CBER-2022-1614-0092397

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2002'	System	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2002'	System	10 Aug 2020 20:05:52

US3142161

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:05:52

US3142161
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:05:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).		15 Oct 2020 13:39:01
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'ConMed list is now updated ' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:44:37
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 11:53:16
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:55
Data point term sent to Coder	System	10 Aug 2020 20:07:08
User entered 'high blood pressure'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'UN UNK 2007'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:48:53
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'Jan 2007'	System	10 Aug 2020 20:06:32

US3142161
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:27:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '2007'	System	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:06:32

US3142161

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered empty.	System	10 Aug 2020 20:06:32

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered '09:51'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 09:51'	System	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered '63' in	Meghan York (b) (4)	10 Aug 2020 20:07:58
DataPoint set to visible.	(b) (4) System	08 Aug 2020 16:33:41

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered '183' lb	Meghan York (b) (4)	10 Aug 2020 20:07:58
DataPoint set to visible.	(b) (4) System	08 Aug 2020 16:33:41

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
Amendment Manager: User entered '32.48478'	System	16 Sep 2020 23:48:43
User entered '32.5'	System	10 Aug 2020 20:07:58
DataPoint set to visible.	System	08 Aug 2020 16:33:41

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'kg/m2'	System	10 Aug 2020 20:07:58
DataPoint set to visible.	System	08 Aug 2020 16:33:41

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).		30 Sep 2020 17:09:43
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:07:38
User entered '98' F	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

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US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered 'temporal'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered '80'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'bpm'	System	10 Aug 2020 20:07:58

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered '14'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'breaths/min'	System	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered '166'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:55
User entered '78'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:07:58

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:07:58

US3142161

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23

US3142161
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23

US3142161
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:44
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:08:07

US3142161

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:55:44
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:08:07

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:27:33

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered 'UN UNK 2002'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:06
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:11

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:27:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:27:33
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:27:33
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered '1'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:27:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered '0'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:07
User entered empty.	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:33

US3142161
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		03 Nov 2020 06:31:44
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'now entered. Information is correct ' (Site from DM).	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:09:05
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:33:29
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:55

US3142161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:34
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:55

US3142161
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:34
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:09:55

US3142161
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'VISIT1'	System	10 Aug 2020 20:09:55

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 16:15:43

US3142161
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:27:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:57:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:05:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:05:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 16:15:43
User entered '185300' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 16:15:43

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 16:15:43

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:10:07

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:10:07

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:10:07

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:10:07

US3142161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:02
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:10:07

US3142161
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:20
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:09:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:40:32
User entered '63' in	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

FDA-CBER-2022-1614-0092479

US3142161
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User entered '183' lb	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:20
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:09:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:40:32
User entered '63' in	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

FDA-CBER-2022-1614-0092481

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User entered '183' lb	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:27:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '09:51'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 09:51'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '98' F	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'temporal'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '80'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:27:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'bpm'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '14'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'breaths/min'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:48:43
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:48:43
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:48:43
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Aug 2020 20:12:44
User entered '166'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '78'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:12:44

US3142161
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:20
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:09:52
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:40:32
User entered '63' in	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:57:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:47:23
User entered '183' lb	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		17 Aug 2020 16:37:07
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:12:44
User entered '10:52'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 10:52'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '99.2' F	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered 'temporal'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '75'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'bpm'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '12'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'breaths/min'	System	10 Aug 2020 20:12:44

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US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:48:43
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:48:43
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:48:43
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Aug 2020 20:12:44
User entered '156'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:35:53
User entered '96'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'mmHg'	System	10 Aug 2020 20:12:44

US3142161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:03:50
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:51
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:13:02

US3142161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:03:52
User entered empty; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:07:51
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:13:02

US3142161
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:04
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:40
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:41
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 16:34:08

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:43
User entered '08 Aug 2020'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:47
User entered '10:22'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '08 Aug 2020 10:22'	System	08 Aug 2020 16:34:08

US3142161
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:04:45
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 16:34:08

US3142161
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:27:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
DataPoint Verified.		12 Nov 2020 00:04:52
User entered 'ONCE'	System	08 Aug 2020 16:34:08

US3142161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 16:34:08

US3142161
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:27:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:07
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:13:38

US3142161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:09
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:13:38

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:11
User entered '09:58'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:13:38

US3142161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 09:58'	System	10 Aug 2020 20:13:38

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:05:33
User entered '8 Aug 2020'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	9 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:33
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:33
User entered '09:58'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 09:58'	System	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:33
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:05:33
User entered '09:58'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:01

US3142161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '8 Aug 2020 09:58'	System	10 Aug 2020 20:14:01

US3142161
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:43:54
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	10 Aug 2020 20:14:05

US3142161
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1'	System	10 Aug 2020 20:14:05

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:57:36', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '2d028c45-bc6e-4c3d-846e-897f9196dec3'	System	08 Aug 2020 16:58:01
User entered 'Yes (Y)'	System	08 Aug 2020 16:58:01

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:57:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '2d028c45-bc6e-4c3d-846e-897f9196dec3'	System	08 Aug 2020 16:58:01
User entered '99.2'	System	08 Aug 2020 16:58:01

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:57:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '2d028c45-bc6e-4c3d-846e-897f9196dec3'	System	08 Aug 2020 16:58:01
User entered 'No (N)'	System	08 Aug 2020 16:58:01

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:57:56', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '2d028c45-bc6e-4c3d-846e-897f9196dec3'	System	08 Aug 2020 16:58:01
User entered '08 Aug 2020 10:57'	System	08 Aug 2020 16:58:01

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:24:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '34210459-1211-44c7-bafb-f9956a661937'	System	09 Aug 2020 15:25:03
User entered 'Yes (Y)'	System	09 Aug 2020 15:25:03

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:24:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '34210459-1211-44c7-bafb-f9956a661937'	System	09 Aug 2020 15:25:03
User entered '98.0'	System	09 Aug 2020 15:25:03

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:24:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '34210459-1211-44c7-bafb-f9956a661937'	System	09 Aug 2020 15:25:03
User entered 'No (N)'	System	09 Aug 2020 15:25:03

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:25:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '34210459-1211-44c7-bafb-f9956a661937'	System	09 Aug 2020 15:25:03
User entered '09 Aug 2020 09:25'	System	09 Aug 2020 15:25:03

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 2'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:06', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '11f77007-a9e4-4e05-be6c-3410c9f55dbf'	System	09 Aug 2020 22:11:30
User entered 'Yes (Y)'	System	09 Aug 2020 22:11:30

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '11f77007-a9e4-4e05-be6c-3410c9f55dbf'	System	09 Aug 2020 22:11:30
User entered '98.0'	System	09 Aug 2020 22:11:30

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '11f77007-a9e4-4e05-be6c-3410c9f55dbf'	System	09 Aug 2020 22:11:30
User entered 'No (N)'	System	09 Aug 2020 22:11:30

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '11f77007-a9e4-4e05-be6c-3410c9f55dbf'	System	09 Aug 2020 22:11:30
User entered '09 Aug 2020 16:11'	System	09 Aug 2020 22:11:30

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 3'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:21:36', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8b2257ad-bacb-4566-a8be-2c2cc0c8b35e'	System	10 Aug 2020 20:22:00
User entered 'Yes (Y)'	System	10 Aug 2020 20:22:00

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:21:50', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8b2257ad-bacb-4566-a8be-2c2cc0c8b35e'	System	10 Aug 2020 20:22:00
User entered '97.8'	System	10 Aug 2020 20:22:00

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:21:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8b2257ad-bacb-4566-a8be-2c2cc0c8b35e'	System	10 Aug 2020 20:22:00
User entered 'No (N)'	System	10 Aug 2020 20:22:00

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:21:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8b2257ad-bacb-4566-a8be-2c2cc0c8b35e'	System	10 Aug 2020 20:22:00
User entered '10 Aug 2020 14:21'	System	10 Aug 2020 20:22:00

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 4'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:01:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '92c66658-0864-43f9-9122-a4d3bd633d66'	System	11 Aug 2020 18:01:37
User entered 'Yes (Y)'	System	11 Aug 2020 18:01:37

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:01:21', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '92c66658-0864-43f9-9122-a4d3bd633d66'	System	11 Aug 2020 18:01:37
User entered '98.5'	System	11 Aug 2020 18:01:37

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:01:27', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '92c66658-0864-43f9-9122-a4d3bd633d66'	System	11 Aug 2020 18:01:37
User entered 'No (N)'	System	11 Aug 2020 18:01:37

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:01:31', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '92c66658-0864-43f9-9122-a4d3bd633d66'	System	11 Aug 2020 18:01:37
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 18:01:37

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

FDA-CBER-2022-1614-0092578

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 5'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ac2893be-965d-4bc1-9c9c-27c0c0a217a7'	System	12 Aug 2020 19:41:30
User entered 'Yes (Y)'	System	12 Aug 2020 19:41:30

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ac2893be-965d-4bc1-9c9c-27c0c0a217a7'	System	12 Aug 2020 19:41:30
User entered '98.7'	System	12 Aug 2020 19:41:30

FDA-CBER-2022-1614-0092581

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ac2893be-965d-4bc1-9c9c-27c0c0a217a7'	System	12 Aug 2020 19:41:30
User entered 'No (N)'	System	12 Aug 2020 19:41:30

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:27', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ac2893be-965d-4bc1-9c9c-27c0c0a217a7'	System	12 Aug 2020 19:41:30
User entered '12 Aug 2020 13:41'	System	12 Aug 2020 19:41:30

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 6'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fde72cf4-7553-4741-950b-c7548d9b44d8'	System	13 Aug 2020 18:30:40
User entered 'Yes (Y)'	System	13 Aug 2020 18:30:40

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:30', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fde72cf4-7553-4741-950b-c7548d9b44d8'	System	13 Aug 2020 18:30:40
User entered '97.5'	System	13 Aug 2020 18:30:40

FDA-CBER-2022-1614-0092588

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:33', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fde72cf4-7553-4741-950b-c7548d9b44d8'	System	13 Aug 2020 18:30:40
User entered 'No (N)'	System	13 Aug 2020 18:30:40

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fde72cf4-7553-4741-950b-c7548d9b44d8'	System	13 Aug 2020 18:30:40
User entered '13 Aug 2020 12:30'	System	13 Aug 2020 18:30:40

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 7'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:27:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:05:27', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'afb38a69-e56a-4a5d-b65d-88686aa8a455'	System	14 Aug 2020 18:05:50
User entered 'Yes (Y)'	System	14 Aug 2020 18:05:50

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:05:38', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'afb38a69-e56a-4a5d-b65d-88686aa8a455'	System	14 Aug 2020 18:05:50
User entered '98.2'	System	14 Aug 2020 18:05:50

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:05:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'afb38a69-e56a-4a5d-b65d-88686aa8a455'	System	14 Aug 2020 18:05:50
User entered 'No (N)'	System	14 Aug 2020 18:05:50

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:05:48', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'afb38a69-e56a-4a5d-b65d-88686aa8a455'	System	14 Aug 2020 18:05:50
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 18:05:50

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:08', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'dda79d43-308f-40bc-84ed-a0435419b9a9'	System	08 Aug 2020 16:58:31
User entered 'None (1)'	System	08 Aug 2020 16:58:31

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'dda79d43-308f-40bc-84ed-a0435419b9a9'	System	08 Aug 2020 16:58:31
User entered 'No (N)'	System	08 Aug 2020 16:58:31

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'dda79d43-308f-40bc-84ed-a0435419b9a9'	System	08 Aug 2020 16:58:31
User entered 'No (N)'	System	08 Aug 2020 16:58:31

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'dda79d43-308f-40bc-84ed-a0435419b9a9'	System	08 Aug 2020 16:58:31
User entered 'None (1)'	System	08 Aug 2020 16:58:31

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'dda79d43-308f-40bc-84ed-a0435419b9a9'	System	08 Aug 2020 16:58:31
User entered '08 Aug 2020 10:58'	System	08 Aug 2020 16:58:31

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 16:34:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 16:34:08

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US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:25:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered 'None (1)'	System	09 Aug 2020 15:26:11

FDA-CBER-2022-1614-0092609

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:25:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered 'Yes (Y)'	System	09 Aug 2020 15:26:11

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:25:53', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered '4'	System	09 Aug 2020 15:26:11

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:25:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered 'No (N)'	System	09 Aug 2020 15:26:11

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered 'None (1)'	System	09 Aug 2020 15:26:11

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '80a062db-2554-497d-a0da-71c69e3fff5f'	System	09 Aug 2020 15:26:11
User entered '09 Aug 2020 09:26'	System	09 Aug 2020 15:26:11

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 2'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17

FDA-CBER-2022-1614-0092619

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
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)	05 Mar 2021 01:49:17

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 3'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35d632c6-9e6f-40b0-8195-6763f5a5efa9'	System	10 Aug 2020 20:22:30
User entered 'None (1)'	System	10 Aug 2020 20:22:30

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:15', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35d632c6-9e6f-40b0-8195-6763f5a5efa9'	System	10 Aug 2020 20:22:30
User entered 'No (N)'	System	10 Aug 2020 20:22:30

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:18', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35d632c6-9e6f-40b0-8195-6763f5a5efa9'	System	10 Aug 2020 20:22:30
User entered 'No (N)'	System	10 Aug 2020 20:22:30

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:23', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35d632c6-9e6f-40b0-8195-6763f5a5efa9'	System	10 Aug 2020 20:22:30
User entered 'None (1)'	System	10 Aug 2020 20:22:30

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:26', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35d632c6-9e6f-40b0-8195-6763f5a5efa9'	System	10 Aug 2020 20:22:30
User entered '10 Aug 2020 14:22'	System	10 Aug 2020 20:22:30

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 4'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:13', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7c1e6d6b-6eb1-4ed0-be8e-4a60af579562'	System	11 Aug 2020 18:02:27
User entered 'None (1)'	System	11 Aug 2020 18:02:27

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7c1e6d6b-6eb1-4ed0-be8e-4a60af579562'	System	11 Aug 2020 18:02:27
User entered 'No (N)'	System	11 Aug 2020 18:02:27

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7c1e6d6b-6eb1-4ed0-be8e-4a60af579562'	System	11 Aug 2020 18:02:27
User entered 'No (N)'	System	11 Aug 2020 18:02:27

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:21', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7c1e6d6b-6eb1-4ed0-be8e-4a60af579562'	System	11 Aug 2020 18:02:27
User entered 'None (1)'	System	11 Aug 2020 18:02:27

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:24', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7c1e6d6b-6eb1-4ed0-be8e-4a60af579562'	System	11 Aug 2020 18:02:27
User entered '11 Aug 2020 12:02'	System	11 Aug 2020 18:02:27

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 5'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:38', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '69ce3a61-4985-4eb6-9d0f-06dc6b1ab979'	System	12 Aug 2020 19:41:53
User entered 'None (1)'	System	12 Aug 2020 19:41:53

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '69ce3a61-4985-4eb6-9d0f-06dc6b1ab979'	System	12 Aug 2020 19:41:53
User entered 'No (N)'	System	12 Aug 2020 19:41:53

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '69ce3a61-4985-4eb6-9d0f-06dc6b1ab979'	System	12 Aug 2020 19:41:53
User entered 'No (N)'	System	12 Aug 2020 19:41:53

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '69ce3a61-4985-4eb6-9d0f-06dc6b1ab979'	System	12 Aug 2020 19:41:53
User entered 'None (1)'	System	12 Aug 2020 19:41:53

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '69ce3a61-4985-4eb6-9d0f-06dc6b1ab979'	System	12 Aug 2020 19:41:53
User entered '12 Aug 2020 13:41'	System	12 Aug 2020 19:41:53

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 6'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4391685d-e3b8-4716-9524-a72f8598876a'	System	13 Aug 2020 18:31:01
User entered 'None (1)'	System	13 Aug 2020 18:31:01

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4391685d-e3b8-4716-9524-a72f8598876a'	System	13 Aug 2020 18:31:01
User entered 'No (N)'	System	13 Aug 2020 18:31:01

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4391685d-e3b8-4716-9524-a72f8598876a'	System	13 Aug 2020 18:31:01
User entered 'No (N)'	System	13 Aug 2020 18:31:01

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:56', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4391685d-e3b8-4716-9524-a72f8598876a'	System	13 Aug 2020 18:31:01
User entered 'None (1)'	System	13 Aug 2020 18:31:01

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:30:59', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4391685d-e3b8-4716-9524-a72f8598876a'	System	13 Aug 2020 18:31:01
User entered '13 Aug 2020 12:30'	System	13 Aug 2020 18:31:01

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 7'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '45eda4de-b805-4a9d-852f-d9a6ef7b4ab1'	System	14 Aug 2020 18:06:25
User entered 'None (1)'	System	14 Aug 2020 18:06:25

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:05', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '45eda4de-b805-4a9d-852f-d9a6ef7b4ab1'	System	14 Aug 2020 18:06:25
User entered 'No (N)'	System	14 Aug 2020 18:06:25

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:08', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '45eda4de-b805-4a9d-852f-d9a6ef7b4ab1'	System	14 Aug 2020 18:06:25
User entered 'No (N)'	System	14 Aug 2020 18:06:25

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '45eda4de-b805-4a9d-852f-d9a6ef7b4ab1'	System	14 Aug 2020 18:06:25
User entered 'None (1)'	System	14 Aug 2020 18:06:25

US3142161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:17', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '45eda4de-b805-4a9d-852f-d9a6ef7b4ab1'	System	14 Aug 2020 18:06:25
User entered '14 Aug 2020 12:06'	System	14 Aug 2020 18:06:25

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:38', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:50', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'None (0)'	System	08 Aug 2020 16:59:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:58:59', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered 'No (N)'	System	08 Aug 2020 16:59:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-08T10:59:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '40bec799-51e7-47f0-bfb6-0b37a4038129'	System	08 Aug 2020 16:59:08
User entered '08 Aug 2020 10:59'	System	08 Aug 2020 16:59:08

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:50', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:53', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'None (0)'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:26:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered 'No (N)'	System	09 Aug 2020 15:27:02

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T09:27:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '8bf5a360-bb2b-45d6-9ac9-08559c2e8cdf'	System	09 Aug 2020 15:27:02
User entered '09 Aug 2020 09:27'	System	09 Aug 2020 15:27:02

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 2'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:35', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:37', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:43', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:45', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'None (0)'	System	09 Aug 2020 22:11:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:48', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered 'No (N)'	System	09 Aug 2020 22:11:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-09T16:11:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5542c961-9948-4885-83e6-6f371d0dc9ba'	System	09 Aug 2020 22:11:52
User entered '09 Aug 2020 16:11'	System	09 Aug 2020 22:11:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 3'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:32', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:35', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'None (0)'	System	10 Aug 2020 20:22:58

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:52', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered 'No (N)'	System	10 Aug 2020 20:22:58

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-10T14:22:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3f249070-0d63-4dbb-81d5-6138b04d6960'	System	10 Aug 2020 20:22:58
User entered '10 Aug 2020 14:22'	System	10 Aug 2020 20:22:58

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 4'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:31', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:34', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:37', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'None (0)'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered 'No (N)'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-11T12:02:48', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '36eabaa5-c005-47dd-b826-e80050ff0e66'	System	11 Aug 2020 18:02:52
User entered '11 Aug 2020 12:02'	System	11 Aug 2020 18:02:52

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 5'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:41:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:07', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'None (0)'	System	12 Aug 2020 19:42:18

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:12', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered 'No (N)'	System	12 Aug 2020 19:42:18

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-12T13:42:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '352566a7-981b-4891-a7db-e55d07181cb3'	System	12 Aug 2020 19:42:18
User entered '12 Aug 2020 13:42'	System	12 Aug 2020 19:42:18

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 6'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:07', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:10', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:13', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'None (0)'	System	13 Aug 2020 18:31:28

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:23', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered 'No (N)'	System	13 Aug 2020 18:31:28

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-13T12:31:26', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3ed536b1-3a56-4298-a6b8-89540e94d238'	System	13 Aug 2020 18:31:28
User entered '13 Aug 2020 12:31'	System	13 Aug 2020 18:31:28

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 7'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:24', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:27', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:30', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:33', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:37', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'None (0)'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered 'No (N)'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-08-14T12:06:43', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a7b5cc88-6da6-464d-a624-05d86c51dc71'	System	14 Aug 2020 18:06:46
User entered '14 Aug 2020 12:06'	System	14 Aug 2020 18:06:46

US3142161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 16:34:08

US3142161
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:52
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:08:21

US3142161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:52
User entered '17 Aug 2020'	Jill York (b) (4)	22 Oct 2020 22:08:21

US3142161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:09:52
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	22 Oct 2020 22:08:21

US3142161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:09:52
User entered empty.	Jill York (b) (4)	22 Oct 2020 22:08:21

US3142161
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:10:29
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:11

US3142161
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1'	System	01 Sep 2020 22:40:11

US3142161
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:23
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:08:40

US3142161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User closed query 'Please reconcile month with SD.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 23:02:18
DataPoint Verified.		18 Nov 2020 23:02:15
Query 'Please reconcile month with SD.' answered with 'done' (Site from CRA).	Meghan York (b) (4) (b) (4)	12 Nov 2020 19:32:47
User entered '24 Aug 2020' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	12 Nov 2020 19:32:39
User opened query 'Please reconcile month with SD.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:14:30
User closed query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' (Site from DM).		03 Nov 2020 15:36:46
Query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' answered with 'date is correct ' (Site from DM).	Meghan York (b) (4) (b) (4)	29 Oct 2020 19:22:47
User opened query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:54:26
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		27 Oct 2020 02:39:35
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '.' (Site from System).	Jill York (b) (4)	22 Oct 2020 22:08:49
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Oct 2020 22:08:40
User entered '24 Sep 2020'	Jill York (b) (4)	22 Oct 2020 22:08:40

Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:11:25
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	22 Oct 2020 22:08:40

US3142161
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:11:27
User entered empty.	Jill York (b) (4)	22 Oct 2020 22:08:40

US3142161
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:39:38
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:18

US3142161
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1'	System	01 Sep 2020 22:40:18

US3142161
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:15:35
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:09:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:15:35
User entered '31 Aug 2020'	Jill York (b) (4)	22 Oct 2020 22:09:15

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US3142161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:15:35
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	22 Oct 2020 22:09:15

US3142161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:15:35
User entered empty.	Jill York (b) (4)	22 Oct 2020 22:09:15

US3142161
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:03
DataPoint Un-verified.		12 Nov 2020 00:15:55
DataPoint Verified.		12 Nov 2020 00:15:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:24

US3142161
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:23
User entered '1'	System	01 Sep 2020 22:40:24

US3142161
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:34
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:09:28

US3142161
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:34
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:09:28

US3142161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:34
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:09:28

US3142161
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'VISIT2'	System	21 Oct 2020 17:09:28

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '15:30'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 15:30'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '98.3' F	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'temporal'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '75'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'bpm'	System	21 Oct 2020 17:10:58

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US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '14'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'breaths/min'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '134'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '84'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

FDA-CBER-2022-1614-0092794

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '16:22'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 16:22'	System	21 Oct 2020 17:10:58

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '98.3' F	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'Other (Other)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered 'temporal'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '72'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

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Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'bpm'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '12'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'breaths/min'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '134'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:17:52
User entered '80'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:10:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	21 Oct 2020 17:10:58

US3142161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:18:42
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:09

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:18:43
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:09

US3142161
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:27:33

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:18:52
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:01
User entered empty.	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:03
User entered empty.	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

FDA-CBER-2022-1614-0092813

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:05
User entered '9 Sep 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Sep 2020 21:56:42
User entered '1 Sep 2020'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:07
User entered '15:52' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Sep 2020 21:56:42
User entered '10:43'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 15:52'	System	09 Sep 2020 21:56:42
User entered '1 Sep 2020 10:43'	System	01 Sep 2020 22:40:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:12
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:40:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		12 Nov 2020 00:19:14
User entered 'ONCE'	System	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 22:40:55

US3142161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:29

US3142161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:51
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:29

US3142161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:19:47
User entered '15:34'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:29

US3142161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 15:34'	System	21 Oct 2020 17:11:29

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:08
User entered '9 Sep 2020'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:08
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:08
User entered '15:30'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 15:30'	System	21 Oct 2020 17:11:48

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:27:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:08
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:08
User entered '15:30'	Meghan York (b) (4) (b) (4)	21 Oct 2020 17:11:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '9 Sep 2020 15:30'	System	21 Oct 2020 17:11:48

US3142161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 00:20:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:22

US3142161
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	24 Sep 2020 15:03:22

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:24:30', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3aae8193-10ad-412c-b5d0-ce841e1130f3'	System	09 Sep 2020 22:24:48
User entered 'Yes (Y)'	System	09 Sep 2020 22:24:48

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:24:38', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3aae8193-10ad-412c-b5d0-ce841e1130f3'	System	09 Sep 2020 22:24:48
User entered '98.3'	System	09 Sep 2020 22:24:48

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:24:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3aae8193-10ad-412c-b5d0-ce841e1130f3'	System	09 Sep 2020 22:24:48
User entered 'No (N)'	System	09 Sep 2020 22:24:48

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:24:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3aae8193-10ad-412c-b5d0-ce841e1130f3'	System	09 Sep 2020 22:24:48
User entered '09 Sep 2020 16:24'	System	09 Sep 2020 22:24:48

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 11:03'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 18:42'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 13:33'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f241c39-3bc8-4d2b-bf82-5ad74d7ee124'	System	10 Sep 2020 15:06:44
User entered 'Yes (Y)'	System	10 Sep 2020 15:06:44

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:36', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f241c39-3bc8-4d2b-bf82-5ad74d7ee124'	System	10 Sep 2020 15:06:44
User entered '98.3'	System	10 Sep 2020 15:06:44

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f241c39-3bc8-4d2b-bf82-5ad74d7ee124'	System	10 Sep 2020 15:06:44
User entered 'No (N)'	System	10 Sep 2020 15:06:44

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f241c39-3bc8-4d2b-bf82-5ad74d7ee124'	System	10 Sep 2020 15:06:44
User entered '10 Sep 2020 09:06'	System	10 Sep 2020 15:06:44

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 19:37'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 14:28'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 2'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:57:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '15c072ab-44f0-442a-a3ff-a2cf1fcabf21'	System	11 Sep 2020 15:58:40
User entered 'Yes (Y)'	System	11 Sep 2020 15:58:40

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:57:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '15c072ab-44f0-442a-a3ff-a2cf1fcabf21'	System	11 Sep 2020 15:58:40
User entered '97.1'	System	11 Sep 2020 15:58:40

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:57:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '15c072ab-44f0-442a-a3ff-a2cf1fcabf21'	System	11 Sep 2020 15:58:40
User entered 'No (N)'	System	11 Sep 2020 15:58:40

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '15c072ab-44f0-442a-a3ff-a2cf1fcabf21'	System	11 Sep 2020 15:58:40
User entered '11 Sep 2020 09:58'	System	11 Sep 2020 15:58:40

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 3'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a3f963d8-1841-405e-9e62-6b66aa6f9831'	System	12 Sep 2020 15:39:18
User entered 'Yes (Y)'	System	12 Sep 2020 15:39:18

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:08', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a3f963d8-1841-405e-9e62-6b66aa6f9831'	System	12 Sep 2020 15:39:18
User entered '97.6'	System	12 Sep 2020 15:39:18

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:13', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a3f963d8-1841-405e-9e62-6b66aa6f9831'	System	12 Sep 2020 15:39:18
User entered 'No (N)'	System	12 Sep 2020 15:39:18

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a3f963d8-1841-405e-9e62-6b66aa6f9831'	System	12 Sep 2020 15:39:18
User entered '12 Sep 2020 09:39'	System	12 Sep 2020 15:39:18

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 4'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:35:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0dce929-ff33-4ac4-8ccd-bacb0e669df6'	System	13 Sep 2020 15:36:24
User entered 'Yes (Y)'	System	13 Sep 2020 15:36:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0dce929-ff33-4ac4-8ccd-bacb0e669df6'	System	13 Sep 2020 15:36:24
User entered '98.5'	System	13 Sep 2020 15:36:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:19', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0dce929-ff33-4ac4-8ccd-bacb0e669df6'	System	13 Sep 2020 15:36:24
User entered 'No (N)'	System	13 Sep 2020 15:36:24

FDA-CBER-2022-1614-0092867

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0dce929-ff33-4ac4-8ccd-bacb0e669df6'	System	13 Sep 2020 15:36:24
User entered '13 Sep 2020 09:36'	System	13 Sep 2020 15:36:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 5'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:17:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '378a3147-6aaa-4160-929d-001d8af97666'	System	14 Sep 2020 14:18:17
User entered 'Yes (Y)'	System	14 Sep 2020 14:18:17

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '378a3147-6aaa-4160-929d-001d8af97666'	System	14 Sep 2020 14:18:17
User entered '98.3'	System	14 Sep 2020 14:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '378a3147-6aaa-4160-929d-001d8af97666'	System	14 Sep 2020 14:18:17
User entered 'No (N)'	System	14 Sep 2020 14:18:17

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:15', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '378a3147-6aaa-4160-929d-001d8af97666'	System	14 Sep 2020 14:18:17
User entered '14 Sep 2020 08:18'	System	14 Sep 2020 14:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 6'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:18:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0cd148d-ffac-4252-b527-b6ada8e158d8'	System	15 Sep 2020 11:19:24
User entered 'Yes (Y)'	System	15 Sep 2020 11:19:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0cd148d-ffac-4252-b527-b6ada8e158d8'	System	15 Sep 2020 11:19:24
User entered '97.5'	System	15 Sep 2020 11:19:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:07', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0cd148d-ffac-4252-b527-b6ada8e158d8'	System	15 Sep 2020 11:19:24
User entered 'No (N)'	System	15 Sep 2020 11:19:24

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:21', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c0cd148d-ffac-4252-b527-b6ada8e158d8'	System	15 Sep 2020 11:19:24
User entered '15 Sep 2020 05:19'	System	15 Sep 2020 11:19:24

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 7'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:09:42', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f7853ad-470d-4f92-9c31-2f75918964d1'	System	16 Sep 2020 16:09:56
User entered 'Yes (Y)'	System	16 Sep 2020 16:09:56

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:09:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f7853ad-470d-4f92-9c31-2f75918964d1'	System	16 Sep 2020 16:09:56
User entered '97.9'	System	16 Sep 2020 16:09:56

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:09:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f7853ad-470d-4f92-9c31-2f75918964d1'	System	16 Sep 2020 16:09:56
User entered 'No (N)'	System	16 Sep 2020 16:09:56

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US3142161
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:09:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '5f7853ad-470d-4f92-9c31-2f75918964d1'	System	16 Sep 2020 16:09:56
User entered '16 Sep 2020 10:09'	System	16 Sep 2020 16:09:56

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:17:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '501f93c4-82b1-49be-a6e4-a0b9c86dac6f'	System	09 Sep 2020 22:18:17
User entered 'None (1)'	System	09 Sep 2020 22:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:17:59', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '501f93c4-82b1-49be-a6e4-a0b9c86dac6f'	System	09 Sep 2020 22:18:17
User entered 'No (N)'	System	09 Sep 2020 22:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:05', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '501f93c4-82b1-49be-a6e4-a0b9c86dac6f'	System	09 Sep 2020 22:18:17
User entered 'No (N)'	System	09 Sep 2020 22:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '501f93c4-82b1-49be-a6e4-a0b9c86dac6f'	System	09 Sep 2020 22:18:17
User entered 'None (1)'	System	09 Sep 2020 22:18:17

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:13', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '501f93c4-82b1-49be-a6e4-a0b9c86dac6f'	System	09 Sep 2020 22:18:17
User entered '09 Sep 2020 16:18'	System	09 Sep 2020 22:18:17

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 11:03'	System	01 Sep 2020 22:40:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 18:42'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 13:33'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '6e22f560-1ba7-44b1-ab25-154cd1628bc1'	System	10 Sep 2020 15:07:02
User entered 'None (1)'	System	10 Sep 2020 15:07:02

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '6e22f560-1ba7-44b1-ab25-154cd1628bc1'	System	10 Sep 2020 15:07:02
User entered 'No (N)'	System	10 Sep 2020 15:07:02

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '6e22f560-1ba7-44b1-ab25-154cd1628bc1'	System	10 Sep 2020 15:07:02
User entered 'No (N)'	System	10 Sep 2020 15:07:02

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:06:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '6e22f560-1ba7-44b1-ab25-154cd1628bc1'	System	10 Sep 2020 15:07:02
User entered 'None (1)'	System	10 Sep 2020 15:07:02

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '6e22f560-1ba7-44b1-ab25-154cd1628bc1'	System	10 Sep 2020 15:07:02
User entered '10 Sep 2020 09:07'	System	10 Sep 2020 15:07:02

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 19:37'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 14:28'	System	01 Sep 2020 22:40:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

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US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 2'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:11', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'df3e6ce4-67f1-4a94-89ea-d908f4073bdd'	System	11 Sep 2020 15:58:48
User entered 'None (1)'	System	11 Sep 2020 15:58:48

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:15', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'df3e6ce4-67f1-4a94-89ea-d908f4073bdd'	System	11 Sep 2020 15:58:48
User entered 'No (N)'	System	11 Sep 2020 15:58:48

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:18', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'df3e6ce4-67f1-4a94-89ea-d908f4073bdd'	System	11 Sep 2020 15:58:48
User entered 'No (N)'	System	11 Sep 2020 15:58:48

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:23', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'df3e6ce4-67f1-4a94-89ea-d908f4073bdd'	System	11 Sep 2020 15:58:48
User entered 'None (1)'	System	11 Sep 2020 15:58:48

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'df3e6ce4-67f1-4a94-89ea-d908f4073bdd'	System	11 Sep 2020 15:58:48
User entered '11 Sep 2020 09:58'	System	11 Sep 2020 15:58:48

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

FDA-CBER-2022-1614-0092914

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 3'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:24', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '747b8d31-b75d-49b9-8dfa-0fc0bed1bfb6'	System	12 Sep 2020 15:39:49
User entered 'None (1)'	System	12 Sep 2020 15:39:49

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '747b8d31-b75d-49b9-8dfa-0fc0bed1bfb6'	System	12 Sep 2020 15:39:49
User entered 'No (N)'	System	12 Sep 2020 15:39:49

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:31', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '747b8d31-b75d-49b9-8dfa-0fc0bed1bfb6'	System	12 Sep 2020 15:39:49
User entered 'No (N)'	System	12 Sep 2020 15:39:49

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:43', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '747b8d31-b75d-49b9-8dfa-0fc0bed1bfb6'	System	12 Sep 2020 15:39:49
User entered 'None (1)'	System	12 Sep 2020 15:39:49

FDA-CBER-2022-1614-0092920

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '747b8d31-b75d-49b9-8dfa-0fc0bed1bfb6'	System	12 Sep 2020 15:39:49
User entered '12 Sep 2020 09:39'	System	12 Sep 2020 15:39:49

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 4'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3c5d0d5e-145d-4673-918b-ef3c0bf46eb8'	System	13 Sep 2020 15:36:43
User entered 'None (1)'	System	13 Sep 2020 15:36:43

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:32', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3c5d0d5e-145d-4673-918b-ef3c0bf46eb8'	System	13 Sep 2020 15:36:43
User entered 'No (N)'	System	13 Sep 2020 15:36:43

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:34', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3c5d0d5e-145d-4673-918b-ef3c0bf46eb8'	System	13 Sep 2020 15:36:43
User entered 'No (N)'	System	13 Sep 2020 15:36:43

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:39', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3c5d0d5e-145d-4673-918b-ef3c0bf46eb8'	System	13 Sep 2020 15:36:43
User entered 'None (1)'	System	13 Sep 2020 15:36:43

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '3c5d0d5e-145d-4673-918b-ef3c0bf46eb8'	System	13 Sep 2020 15:36:43
User entered '13 Sep 2020 09:36'	System	13 Sep 2020 15:36:43

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 5'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:21', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '02bbd5a9-0c71-42da-b101-603f57b0c7be'	System	14 Sep 2020 14:18:36
User entered 'None (1)'	System	14 Sep 2020 14:18:36

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:24', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '02bbd5a9-0c71-42da-b101-603f57b0c7be'	System	14 Sep 2020 14:18:36
User entered 'No (N)'	System	14 Sep 2020 14:18:36

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:26', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '02bbd5a9-0c71-42da-b101-603f57b0c7be'	System	14 Sep 2020 14:18:36
User entered 'No (N)'	System	14 Sep 2020 14:18:36

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '02bbd5a9-0c71-42da-b101-603f57b0c7be'	System	14 Sep 2020 14:18:36
User entered 'None (1)'	System	14 Sep 2020 14:18:36

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:32', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '02bbd5a9-0c71-42da-b101-603f57b0c7be'	System	14 Sep 2020 14:18:36
User entered '14 Sep 2020 08:18'	System	14 Sep 2020 14:18:36

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 6'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:27', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c7407fce-334e-44a6-a096-ef9369d2230a'	System	15 Sep 2020 11:19:46
User entered 'None (1)'	System	15 Sep 2020 11:19:46

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c7407fce-334e-44a6-a096-ef9369d2230a'	System	15 Sep 2020 11:19:46
User entered 'No (N)'	System	15 Sep 2020 11:19:46

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:33', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c7407fce-334e-44a6-a096-ef9369d2230a'	System	15 Sep 2020 11:19:46
User entered 'No (N)'	System	15 Sep 2020 11:19:46

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c7407fce-334e-44a6-a096-ef9369d2230a'	System	15 Sep 2020 11:19:46
User entered 'None (1)'	System	15 Sep 2020 11:19:46

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:43', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c7407fce-334e-44a6-a096-ef9369d2230a'	System	15 Sep 2020 11:19:46
User entered '15 Sep 2020 05:19'	System	15 Sep 2020 11:19:46

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:27:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 7'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '119ad04e-8b4d-40cf-aa24-5da578ff0c50'	System	16 Sep 2020 16:10:16
User entered 'None (1)'	System	16 Sep 2020 16:10:16

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:03', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '119ad04e-8b4d-40cf-aa24-5da578ff0c50'	System	16 Sep 2020 16:10:16
User entered 'No (N)'	System	16 Sep 2020 16:10:16

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:06', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '119ad04e-8b4d-40cf-aa24-5da578ff0c50'	System	16 Sep 2020 16:10:16
User entered 'No (N)'	System	16 Sep 2020 16:10:16

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '119ad04e-8b4d-40cf-aa24-5da578ff0c50'	System	16 Sep 2020 16:10:16
User entered 'None (1)'	System	16 Sep 2020 16:10:16

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:12', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '119ad04e-8b4d-40cf-aa24-5da578ff0c50'	System	16 Sep 2020 16:10:16
User entered '16 Sep 2020 10:10'	System	16 Sep 2020 16:10:16

US3142161
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:18', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:20', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:31', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:33', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'None (0)'	System	09 Sep 2020 22:18:44

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:37', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered 'No (N)'	System	09 Sep 2020 22:18:44

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-09T16:18:40', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e44b5a08-7c38-4bfa-86ab-b31109126e1d'	System	09 Sep 2020 22:18:44
User entered '09 Sep 2020 16:18'	System	09 Sep 2020 22:18:44

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:27:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 11:03'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 18:42'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 13:33'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:09', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:11', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:13', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:16', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:18', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:20', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'None (0)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered 'No (N)'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-10T09:07:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '35f03c5c-d4a7-46cd-b7dd-4bd8c51bb93f'	System	10 Sep 2020 15:07:29
User entered '10 Sep 2020 09:07'	System	10 Sep 2020 15:07:29

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '09 Sep 2020 19:37'	System	09 Sep 2020 21:56:42
User entered '01 Sep 2020 14:28'	System	01 Sep 2020 22:40:55

FDA-CBER-2022-1614-0092976

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 2'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:45', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:50', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:52', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:58:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'None (0)'	System	11 Sep 2020 15:59:06

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:59:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered 'No (N)'	System	11 Sep 2020 15:59:06

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-11T09:59:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b762f276-2f7a-495f-bd31-49114090f379'	System	11 Sep 2020 15:59:06
User entered '11 Sep 2020 09:59'	System	11 Sep 2020 15:59:06

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 3'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:53', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:56', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:39:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:40:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:40:03', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'None (0)'	System	12 Sep 2020 15:40:12

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:40:08', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered 'No (N)'	System	12 Sep 2020 15:40:12

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-12T09:40:10', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'f5409d76-0fd0-45bd-a16d-4d4b54f80da1'	System	12 Sep 2020 15:40:12
User entered '12 Sep 2020 09:40'	System	12 Sep 2020 15:40:12

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 4'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:53', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:36:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:37:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'None (0)'	System	13 Sep 2020 15:37:09

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:27:33
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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:37:03', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered 'No (N)'	System	13 Sep 2020 15:37:09

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-13T09:37:05', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4c209f5b-e62e-4d05-87d2-3cc1475898b0'	System	13 Sep 2020 15:37:09
User entered '13 Sep 2020 09:37'	System	13 Sep 2020 15:37:09

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 5'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:36', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:43', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:52', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'None (0)'	System	14 Sep 2020 14:19:01

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:18:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered 'No (N)'	System	14 Sep 2020 14:19:01

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-14T08:19:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'c4b82185-b2e3-4dea-9a54-fccb40528f15'	System	14 Sep 2020 14:19:01
User entered '14 Sep 2020 08:19'	System	14 Sep 2020 14:19:01

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 6'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:52', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:55', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:19:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:20:01', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:20:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:20:08', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'None (0)'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:20:11', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered 'No (N)'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-15T05:20:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'b2d26cd7-bb1e-4cae-917f-6652fd10507c'	System	15 Sep 2020 11:20:17
User entered '15 Sep 2020 05:20'	System	15 Sep 2020 11:20:17

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	01 Sep 2020 22:40:55
User entered 'Day 7'	System	01 Sep 2020 22:40:55

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:20', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:23', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:30', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:32', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:27:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:34', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'None (0)'	System	16 Sep 2020 16:10:45

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:38', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered 'No (N)'	System	16 Sep 2020 16:10:45

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-09-16T10:10:41', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '802d43a1-9cc3-4d11-b54a-608a844ade3b'	System	16 Sep 2020 16:10:45
User entered '16 Sep 2020 10:10'	System	16 Sep 2020 16:10:45

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:56:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:40:55

US3142161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:27:33

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:56:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:40:55

US3142161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:03:44
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:09:47

US3142161
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:03:44
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User closed query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:37:00
Query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' answered with 'information is correct ' (Site from DM).	Meghan York (b) (4) (b) (4)	29 Oct 2020 19:23:20
User opened query 'Per CDM: Response to the query is inappropriate. Please review and update the correct response. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:55:03
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		27 Oct 2020 02:39:53
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '.' (Site from System).	Jill York (b) (4)	22 Oct 2020 22:09:54
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Oct 2020 22:09:47
User entered '15 Sep 2020'	Jill York (b) (4)	22 Oct 2020 22:09:47

US3142161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:03:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4) (b) (4)	22 Oct 2020 22:09:47

US3142161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:03:44
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jill York (b) (4)	22 Oct 2020 22:09:47

US3142161

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:40:49
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:31

US3142161
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	24 Sep 2020 15:03:31

US3142161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:42:56
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:53

FDA-CBER-2022-1614-0093050

US3142161
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:42:57
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		24 Sep 2020 15:07:50
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data entered is correct' (Site from System).	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:04:04
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Sep 2020 15:03:53
User entered '22 Sep 2020'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:53

US3142161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:42:59
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:53

US3142161
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:43:01
User entered empty.	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:03:53

US3142161

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:41:05
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:04:10

US3142161
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	24 Sep 2020 15:04:10

US3142161
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:08:11
DataPoint Un-verified.		20 Apr 2021 16:08:07
DataPoint Verified.		20 Apr 2021 16:07:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	29 Sep 2020 21:45:55

US3142161
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:07:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 17:09:34
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data entered is correct' (Site from System).	Jami Wagner (b) (4) (b) (4)	29 Sep 2020 21:46:09
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 21:45:55
User entered '29 Sep 2020'	Jami Wagner (b) (4) (b) (4)	29 Sep 2020 21:45:55

Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:07:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	29 Sep 2020 21:45:55

US3142161
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
DataPoint Verified.		20 Apr 2021 16:07:00
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jami Wagner (b) (4) (b) (4)	29 Sep 2020 21:45:55

US3142161

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:42:21
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	25 Sep 2020 14:27:47

US3142161
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	25 Sep 2020 14:27:47

US3142161
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:44:48
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:10:34

US3142161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:07:34
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		27 Oct 2020 02:46:19
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'visit is out of window due to subject's scheduling issues' (Site from System).	Jill York (b) (4)	22 Oct 2020 22:10:55
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Oct 2020 22:10:34
User entered '22 Oct 2020'	Jill York (b) (4)	22 Oct 2020 22:10:34

US3142161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 21:44:50
User entered 'Clinic (Clinic)'	Jill York (b) (4)	22 Oct 2020 22:10:34

US3142161
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'VISIT3'	System	22 Oct 2020 22:10:34

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '22 Oct 2020'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '15:10'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '22 Oct 2020 15:10'	System	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '97.5' F	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered 'Other (Other)'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered 'temporal'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '89'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'bpm'	System	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '10'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'breaths/min'	System	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '138'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	22 Oct 2020 22:11:42

US3142161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:51:09
User entered '80'	Jill York (b) (4)	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered 'mmHg'	System	22 Oct 2020 22:11:42

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03

US3142161
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:27:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03

US3142161
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:27:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:08:32
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:11:51

US3142161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:08:41
User entered '22 Oct 2020'	Jill York (b) (4)	22 Oct 2020 22:11:51

US3142161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:08:54
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:12:07

US3142161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:08:54
User entered '22 Oct 2020'	Jill York (b) (4)	22 Oct 2020 22:12:07

US3142161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:08:54
User entered '15:37'	Jill York (b) (4)	22 Oct 2020 22:12:07

US3142161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '22 Oct 2020 15:37'	System	22 Oct 2020 22:12:07

US3142161
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:09:04
User entered 'Yes (Y)'	Jill York (b) (4)	22 Oct 2020 22:12:13

US3142161
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	22 Oct 2020 22:12:13

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 64'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-10T12:00:45', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a9e7678d-9a85-4813-9eea-c35568d5768e'	System	10 Oct 2020 18:01:00
User entered 'No (N)'	System	10 Oct 2020 18:01:00

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-10T12:00:48', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a9e7678d-9a85-4813-9eea-c35568d5768e'	System	10 Oct 2020 18:01:00
User entered 'No (N)'	System	10 Oct 2020 18:01:00

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-10T12:00:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'a9e7678d-9a85-4813-9eea-c35568d5768e'	System	10 Oct 2020 18:01:00
User entered '10 Oct 2020 12:00:57'	System	10 Oct 2020 18:01:00

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 71'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-15T00:08:14', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ed4a0990-a355-4d54-a85a-a36abcbc86c2'	System	15 Oct 2020 06:08:30
User entered 'No (N)'	System	15 Oct 2020 06:08:30

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-15T00:08:18', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ed4a0990-a355-4d54-a85a-a36abcbc86c2'	System	15 Oct 2020 06:08:30
User entered 'No (N)'	System	15 Oct 2020 06:08:30

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-15T00:08:26', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'ed4a0990-a355-4d54-a85a-a36abcbc86c2'	System	15 Oct 2020 06:08:30
User entered '15 Oct 2020 00:08:26'	System	15 Oct 2020 06:08:30

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 16:34:08

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 78'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-24T12:07:28', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '60490087-ccb2-40a9-a5e0-7501d63f71a5'	System	24 Oct 2020 18:07:38
User entered 'No (N)'	System	24 Oct 2020 18:07:38

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-24T12:07:31', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '60490087-ccb2-40a9-a5e0-7501d63f71a5'	System	24 Oct 2020 18:07:38
User entered 'No (N)'	System	24 Oct 2020 18:07:38

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-10-24T12:07:36', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '60490087-ccb2-40a9-a5e0-7501d63f71a5'	System	24 Oct 2020 18:07:38
User entered '24 Oct 2020 12:07:36'	System	24 Oct 2020 18:07:38

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 92'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-05T00:01:40', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4b5487cd-1727-43c5-ad80-0a79b9f7c234'	System	05 Nov 2020 07:01:58
User entered 'No (N)'	System	05 Nov 2020 07:01:58

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-05T00:01:49', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4b5487cd-1727-43c5-ad80-0a79b9f7c234'	System	05 Nov 2020 07:01:58
User entered 'No (N)'	System	05 Nov 2020 07:01:58

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-05T00:01:57', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '4b5487cd-1727-43c5-ad80-0a79b9f7c234'	System	05 Nov 2020 07:01:58
User entered '05 Nov 2020 00:01:57'	System	05 Nov 2020 07:01:58

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 99'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-14T13:34:45', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '08d8afee-e4d9-4f38-b502-33fc0e1ed9c6'	System	14 Nov 2020 20:34:59
User entered 'No (N)'	System	14 Nov 2020 20:34:59

FDA-CBER-2022-1614-0093116

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-14T13:34:50', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '08d8afee-e4d9-4f38-b502-33fc0e1ed9c6'	System	14 Nov 2020 20:34:59
User entered 'No (N)'	System	14 Nov 2020 20:34:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-14T13:34:54', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '08d8afee-e4d9-4f38-b502-33fc0e1ed9c6'	System	14 Nov 2020 20:34:59
User entered '14 Nov 2020 13:34:54'	System	14 Nov 2020 20:34:59

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:49:17
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33
Data entry locked.	System	08 Aug 2020 16:34:08
User entered 'Day 106'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please 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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093129

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093142

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please 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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Please 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)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 16:34:08

US3142161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:49
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	06 Apr 2021 17:48:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:34:33
Data entry locked.	System	08 Aug 2020 16:34:08
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 16:34:08

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-23T00:01:32', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'cbffff51-3bdb-4153-9256-c780e7ff646b'	System	23 Nov 2020 07:02:07
User entered 'No (N)'	System	23 Nov 2020 07:02:07

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-23T00:01:46', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'cbffff51-3bdb-4153-9256-c780e7ff646b'	System	23 Nov 2020 07:02:07
User entered 'No (N)'	System	23 Nov 2020 07:02:07

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-11-23T00:02:02', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'cbffff51-3bdb-4153-9256-c780e7ff646b'	System	23 Nov 2020 07:02:07
User entered '23 Nov 2020 00:02:02'	System	23 Nov 2020 07:02:07

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-02T12:00:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '51cdb1cf-8308-40fc-932f-572cf6c322b0'	System	02 Dec 2020 19:01:21
User entered 'No (N)'	System	02 Dec 2020 19:01:21

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-02T12:00:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '51cdb1cf-8308-40fc-932f-572cf6c322b0'	System	02 Dec 2020 19:01:21
User entered 'No (N)'	System	02 Dec 2020 19:01:21

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-02T12:01:17', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '51cdb1cf-8308-40fc-932f-572cf6c322b0'	System	02 Dec 2020 19:01:21
User entered '02 Dec 2020 12:01:17'	System	02 Dec 2020 19:01:21

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093160

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-07T00:01:35', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '62eedb11-13ee-4694-a117-e19cd88f8f50'	System	07 Dec 2020 07:02:07
User entered 'No (N)'	System	07 Dec 2020 07:02:07

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-07T00:01:59', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '62eedb11-13ee-4694-a117-e19cd88f8f50'	System	07 Dec 2020 07:02:07
User entered 'No (N)'	System	07 Dec 2020 07:02:07

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-07T00:02:06', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '62eedb11-13ee-4694-a117-e19cd88f8f50'	System	07 Dec 2020 07:02:07
User entered '07 Dec 2020 00:02:06'	System	07 Dec 2020 07:02:07

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-14T04:22:22', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '75d2ceb4-1847-4ec5-95a3-f38ce77f3c74'	System	14 Dec 2020 11:22:39
User entered 'No (N)'	System	14 Dec 2020 11:22:39

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-14T04:22:30', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '75d2ceb4-1847-4ec5-95a3-f38ce77f3c74'	System	14 Dec 2020 11:22:39
User entered 'No (N)'	System	14 Dec 2020 11:22:39

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-14T04:22:35', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '75d2ceb4-1847-4ec5-95a3-f38ce77f3c74'	System	14 Dec 2020 11:22:39
User entered '14 Dec 2020 04:22:35'	System	14 Dec 2020 11:22:39

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 03:10:57
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'no AE associated with this e-diary entry' (Site from DM).	Jill York (b) (4)	21 Apr 2021 19:04:37
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:00:40', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered 'Yes (Y)'	System	23 Dec 2020 19:01:22

FDA-CBER-2022-1614-0093174

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:00:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered 'No (N)'	System	23 Dec 2020 19:01:22

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:00:51', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered 'No (N)'	System	23 Dec 2020 19:01:22

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:00:58', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered 'Yes (Y)'	System	23 Dec 2020 19:01:22

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:01:07', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 19:01:22

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-23T12:01:11', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '586fdad7-cda3-4de8-bf64-7fad06343ea3'	System	23 Dec 2020 19:01:22
User entered '23 Dec 2020 12:01:11'	System	23 Dec 2020 19:01:22

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:34:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093181

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-29T06:46:05', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '698b2d65-5347-400b-8551-eefe2d6d426a'	System	29 Dec 2020 13:46:19
User entered 'No (N)'	System	29 Dec 2020 13:46:19

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-29T06:46:10', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '698b2d65-5347-400b-8551-eefe2d6d426a'	System	29 Dec 2020 13:46:19
User entered 'No (N)'	System	29 Dec 2020 13:46:19

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2020-12-29T06:46:15', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '698b2d65-5347-400b-8551-eefe2d6d426a'	System	29 Dec 2020 13:46:19
User entered '29 Dec 2020 06:46:15'	System	29 Dec 2020 13:46:19

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093187

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-04T15:24:44', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7e5bff8b-2661-4bc0-af3f-764f33465adc'	System	04 Jan 2021 22:24:54
User entered 'No (N)'	System	04 Jan 2021 22:24:54

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-04T15:24:47', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7e5bff8b-2661-4bc0-af3f-764f33465adc'	System	04 Jan 2021 22:24:54
User entered 'No (N)'	System	04 Jan 2021 22:24:54

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-04T15:24:52', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '7e5bff8b-2661-4bc0-af3f-764f33465adc'	System	04 Jan 2021 22:24:54
User entered '04 Jan 2021 15:24:52'	System	04 Jan 2021 22:24:54

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:34:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-13T12:12:53', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '00e5052c-ec9a-48fb-8133-0501ae97b832'	System	13 Jan 2021 19:13:03
User entered 'No (N)'	System	13 Jan 2021 19:13:03

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-13T12:12:56', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '00e5052c-ec9a-48fb-8133-0501ae97b832'	System	13 Jan 2021 19:13:03
User entered 'No (N)'	System	13 Jan 2021 19:13:03

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-13T12:13:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: '00e5052c-ec9a-48fb-8133-0501ae97b832'	System	13 Jan 2021 19:13:03
User entered '13 Jan 2021 12:13:00'	System	13 Jan 2021 19:13:03

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-18T00:02:00', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fa212e92-9f66-4326-b949-2f2fb4c37dac'	System	18 Jan 2021 07:02:09
User entered 'No (N)'	System	18 Jan 2021 07:02:09

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-18T00:02:04', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fa212e92-9f66-4326-b949-2f2fb4c37dac'	System	18 Jan 2021 07:02:09
User entered 'No (N)'	System	18 Jan 2021 07:02:09

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-18T00:02:07', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'fa212e92-9f66-4326-b949-2f2fb4c37dac'	System	18 Jan 2021 07:02:09
User entered '18 Jan 2021 00:02:07'	System	18 Jan 2021 07:02:09

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093205

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-27T12:00:29', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e81acd21-d90c-4310-a7b5-e041f9f9775d'	System	29 Jan 2021 18:59:27
User entered 'No (N)'	System	29 Jan 2021 18:59:27

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-29T11:59:20', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e81acd21-d90c-4310-a7b5-e041f9f9775d'	System	29 Jan 2021 18:59:27
User entered 'No (N)'	System	29 Jan 2021 18:59:27

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6BCB11B7-116E-4300-A9AF-DAEC0097082B)', Time: '2021-01-29T11:59:25', User OID: 'PatientReportedOutcome (US3142161)', ODM File OID: 'e81acd21-d90c-4310-a7b5-e041f9f9775d'	System	29 Jan 2021 18:59:27
User entered '29 Jan 2021 11:59:25'	System	29 Jan 2021 18:59:27

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:34:33

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:34:33

FDA-CBER-2022-1614-0093214

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:34:33

US3142161
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:27:33
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:34:33

US3142161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:34:33
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:34:33

US3142161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:49:23
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	03 Nov 2020 17:13:23

US3142161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:49:25
User entered '2 Nov 2020'	Jami Wagner (b) (4) (b) (4)	03 Nov 2020 17:13:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:49:26
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	03 Nov 2020 17:13:23

US3142161
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:49:27
User closed query 'Per DM CLR: Comment = FLU SHOT 20OCT2020. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).		02 Dec 2020 19:18:31
Query 'Per DM CLR: Comment = FLU SHOT 20OCT2020. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' answered with 'now updated ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:53
User opened query 'Per DM CLR: Comment = FLU SHOT 20OCT2020. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:02:05
User entered 'Flu shot 20OCT2020'	Jami Wagner (b) (4) (b) (4)	03 Nov 2020 17:13:23

US3142161

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:43:59
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	03 Nov 2020 17:13:28

US3142161

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:03
User entered '1'	System	03 Nov 2020 17:13:28

US3142161
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:18:53
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	07 Dec 2020 20:34:27

US3142161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:18:53
User entered '4 Dec 2020'	Jami Wagner (b) (4) (b) (4)	07 Dec 2020 20:34:27

US3142161
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:18:53
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	07 Dec 2020 20:34:27

US3142161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User closed query 'Please provide SD associated with SAE. ' (Site from CRA).		21 Apr 2021 17:42:28
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
Query 'Please provide SD associated with SAE. ' answered with 'done ' (Site from CRA).	Jill York (b) (4)	16 Apr 2021 17:09:07
User opened query 'Please provide SD associated with SAE. ' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:56:52
User closed query 'Please verify if DX of stroke should be entered as an adverse event and Eliquis should be entered as a con med.' (Site from CRA).		03 Feb 2021 18:56:52
Query 'Please verify if DX of stroke should be entered as an adverse event and Eliquis should be entered as a con med.' answered with 'done ' (Site from CRA).	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:32:14
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 20:18:53
User opened query 'Please verify if DX of stroke should be entered as an adverse event and Eliquis should be entered as a con med.' (Site from CRA).		18 Jan 2021 20:14:58
User entered 'subject has started eliquis 5mg 2x day for stroke. Subject was in ER for 24hrs on 23nov2020'	Jami Wagner (b) (4) (b) (4)	07 Dec 2020 20:34:27

US3142161
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:44:18
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	07 Dec 2020 20:34:32

US3142161
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User entered '1'	System	07 Dec 2020 20:34:32

US3142161
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:36:52
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 16:41:27

US3142161
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:36:52
User entered '4 Jan 2021'	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 16:41:27

US3142161
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:36:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 16:41:27

US3142161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:36:52
User entered empty.	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 16:41:27

US3142161

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:44:51
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 16:41:33

US3142161
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User entered '1'	System	05 Jan 2021 16:41:33

US3142161
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:36:23
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:40:31

US3142161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:36:23
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		11 Feb 2021 20:13:45
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data entered is correct ' (Site from System).	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:40:54
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Feb 2021 23:40:31
User entered '2 Feb 2021'	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:40:31

US3142161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:36:23
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:40:31

US3142161
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:27:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:36:23
User entered empty.	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:40:31

US3142161
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:45:09
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	02 Feb 2021 23:41:05

US3142161
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:27:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:08
User entered '1'	System	02 Feb 2021 23:41:05

US3142161
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33

Was this visit performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered 'No (N)'	Jill York (b) (4)	06 Apr 2021 17:36:01

US3142161
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jill York (b) (4)	06 Apr 2021 17:36:01

US3142161
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jill York (b) (4)	06 Apr 2021 17:36:01

US3142161
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 17:36:01

US3142161

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

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:46:43
User entered 'Yes (Y)'	Jill York (b) (4)	24 Feb 2021 22:22:02

US3142161

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

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:46:43
User entered '24 Feb 2021'	Jill York (b) (4)	24 Feb 2021 22:22:02

US3142161

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

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:46:43
User entered 'Clinic (Clinic)'	Jill York (b) (4)	24 Feb 2021 22:22:02

US3142161
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:27:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 22:22:02

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered '24 Feb 2021'	Jill York (b) (4)	24 Feb 2021 22:22:34

FDA-CBER-2022-1614-0093256

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:59:02

US3142161

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered 'Yes (Y)'	Jill York (b) (4)	24 Feb 2021 22:22:34

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:59:02

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered '24 Feb 2021'	Jill York (b) (4)	24 Feb 2021 22:22:34

US3142161

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered 'Placebo (Placebo)'	Jill York (b) (4)	24 Feb 2021 22:22:34

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered 'Placebo (Placebo)'	Jill York (b) (4)	24 Feb 2021 22:22:34

US3142161

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered 'Placebo (Placebo)'	Jill York (b) (4)	24 Feb 2021 22:22:34

US3142161

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:18
User entered 'No (N)'	Jill York (b) (4)	24 Feb 2021 22:22:34

US3142161
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:27:33

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User entered '1'	System	24 Feb 2021 22:22:34

US3142161

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

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User entered empty.	System	24 Feb 2021 22:22:34

US3142161

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:50
User entered 'No (N)'	Jill York (b) (4)	24 Feb 2021 22:22:58

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:47:50
User entered empty.	Jill York (b) (4)	24 Feb 2021 22:22:58

FDA-CBER-2022-1614-0093268

US3142161

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:47:50
User entered empty.	Jill York (b) (4)	24 Feb 2021 22:22:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User entered empty.	System	24 Feb 2021 22:22:58

FDA-CBER-2022-1614-0093270

US3142161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:48:02
User entered 'No (N)'	Jill York (b) (4)	24 Feb 2021 22:23:04

FDA-CBER-2022-1614-0093271

US3142161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:27:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:48:02
User entered empty.	Jill York (b) (4)	24 Feb 2021 22:23:04

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:48:02
User entered empty.	Jill York (b) (4)	24 Feb 2021 22:23:04

US3142161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:27:33

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:33
User entered empty.	System	24 Feb 2021 22:23:04

FDA-CBER-2022-1614-0093274

US3142161

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:27:33

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:32:04
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:48:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:27:35

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

AEID

Audit	User	Time (GMT)
User closed query 'Please enter AE page in source documents.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:09:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:57:42
Query 'Please enter AE page in source documents.' answered with 'see AE form in source' (Site from CRA).	Jill York (b) (4)	12 Apr 2021 20:45:47
User opened query 'Please enter AE page in source documents.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 19:24:53
DataPoint Verified.		03 Mar 2021 19:20:37
User entered 'USA-US064-2021-mRNA-1273-P301000006'	System	26 Jan 2021 14:35:03
User entered 'New'	(b) (4), (b) (6)	26 Jan 2021 14:35:03

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:44
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 17:30:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 17:30:55
Data point term sent to Coder	System	25 Jan 2021 17:30:26
User entered 'stroke'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:40
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:00
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:08
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:10
User entered '23 Nov 2020'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:19
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 17:29:41

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:21
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Please consider if 24Nov2020 should be the end date due to discharge date from hospital' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:10:04
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
Query 'Please consider if 24Nov2020 should be the end date due to discharge date from hospital' answered with 'the stroke did not last two days. date is correct' (Site from CRA).	Jill York (b) (4)	12 Apr 2021 20:33:57
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:24
User opened query 'Please consider if 24Nov2020 should be the end date due to discharge date from hospital' (Site from CRA).		03 Mar 2021 19:23:57
User entered '23 Nov 2020'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:34
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 17:29:41

Severity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

FDA-CBER-2022-1614-0093288

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:39
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:47
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:49
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:53
User entered '1'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:51
User entered '23 Nov 2020'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:25:56
User entered '24 Nov 2020'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:03
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:06
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:08
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:11
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:14
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:18
User entered 'Not Related (NOT RELATED)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:30
User entered 'Not Related (NOT RELATED)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:23
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User closed query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:55:58
Query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:42:04
DataPoint Un-verified.	Jill York (b) (4)	12 Apr 2021 20:41:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jill York (b) (4)	12 Apr 2021 20:41:58
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:26:33
User opened query 'PV Query: As the last dose of study drug was given on 09 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		03 Feb 2021 16:46:03
User entered 'None (NONE)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:22:21
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'site does not have records' (Site from DM).	Jill York (b) (4)	12 Apr 2021 20:41:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).		19 Feb 2021 04:01:53
User entered '1'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for your response, that site does not have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 22:51:53
User closed query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response. ' (Site from Safety).		03 May 2021 14:20:47
Query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response. ' answered with 'site will request records' (Site from Safety).	Jill York (b) (4)	01 May 2021 17:31:28
User opened query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:04:19
User closed query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' (Site from Safety).		23 Apr 2021 13:27:14
User closed query 'PV Query: Thank you for your response, that the subject experienced signs and symptoms of stroke. Please provide details of these signs and symptoms.' (Site from Safety).		23 Apr 2021 13:26:52

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33
Narrative

Audit	User		Time (GMT)
Query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' answered with 'site will request medical records' (Site from Safety).	Jill York	(b) (4)	22 Apr 2021 17:46:25
Query 'PV Query: Thank you for your response, that the subject experienced signs and symptoms of stroke. Please provide details of these signs and symptoms.' answered with 'it is assumed that she had signs/symptoms of stroke. The exact symptoms are not noted in the source. Site unable to call subject as she has withdrawn consent and does not wish to be contacted.' (Site from Safety).	Jill York	(b) (4)	22 Apr 2021 17:46:07
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)		21 Apr 2021 13:24:23
User opened query 'PV Query: Thank you for your response, that site doesnot have records of the subject. Kindly confirm if medical records will be available in future? If yes then please send the redacted copy to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' (Site from Safety).			21 Apr 2021 13:24:17
User opened query 'PV Query: Thank you for your response, that the subject experienced signs and symptoms of stroke. Please provide details of these signs and symptoms.' (Site from Safety).			21 Apr 2021 13:24:09
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)		18 Apr 2021 20:29:32

US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 13:57:35
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		13 Apr 2021 13:57:32
User closed query 'PV Query: Did the subject experience signs and symptoms of the stroke.' (Site from Safety).		13 Apr 2021 13:57:18
User closed query 'PV Query: Please provide the circumstances surrounding the event.' (Site from Safety).		13 Apr 2021 13:57:13
User closed query 'PV Query: Please provide the etiology of the stroke (what was the underlying cause of the stroke). If unknown please state so.' (Site from Safety).		13 Apr 2021 13:56:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'site does not have records' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:41:17
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'unknown as site does not have hospital records' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:40:53
Query 'PV Query: Did the subject experience signs and symptoms of the stroke.' answered with 'yes' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:40:17

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US3142161
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:27:33
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the circumstances surrounding the event.' answered with 'unknown as site does not yet have records' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:37:52
Query 'PV Query: Please provide the etiology of the stroke (what was the underlying cause of the stroke). If unknown please state so.' answered with 'unknown etiology' (Site from Safety).	Jill York (b) (4)	12 Apr 2021 20:34:30
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:49:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		03 Feb 2021 16:45:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		03 Feb 2021 16:45:51
User opened query 'PV Query: Did the subject experience signs and symptoms of the stroke.' (Site from Safety).		03 Feb 2021 16:40:21
User opened query 'PV Query: Please provide the circumstances surrounding the event.' (Site from Safety).		03 Feb 2021 16:40:15
User opened query 'PV Query: Please provide the etiology of the stroke (what was the underlying cause of the stroke). If unknown please state so.' (Site from Safety).		03 Feb 2021 16:40:10
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 17:30:42
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 17:30:42
User entered 'Subject had a stroke 23Nov2020. Hospitalized for 24 hours' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:30:42

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Narrative

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 17:29:41
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 17:29:41

US3142161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 17:29:41

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:11:51
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:51:49
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:44:58

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:51:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:51:32
Data point term sent to Coder	System	14 Oct 2020 16:50:08
User entered 'aspirin'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

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US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:06:55
DataPoint Verified.		11 Nov 2020 23:52:19
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:17:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:17:42
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:18:49
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

FDA-CBER-2022-1614-0093318

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:26
User entered 'general heart health'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:28
User entered '81'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2013'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:07

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US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:50:07

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:51:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:51:33
Data point term sent to Coder	System	14 Oct 2020 16:51:12
User entered 'Losartan'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

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US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'hypertension'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '50'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2013'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

FDA-CBER-2022-1614-0093347

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:50:38

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:50:38

FDA-CBER-2022-1614-0093351

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:50:38

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:31
Data point term sent to Coder	System	14 Oct 2020 16:52:12
User entered 'Pravastatin'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'high cholesterol'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '40'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2007'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:51:23

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:20:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:20:41
Data point term sent to Coder	System	10 Nov 2020 23:19:21
Coding entries removed.	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:18:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:52:31
Data point term sent to Coder	System	14 Oct 2020 16:52:13
User entered 'Zyrtec'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matched. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:19:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matched. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:19:02
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:18:51
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matched. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:19:18
User entered 'allergies'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '10'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:27:33
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2010'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:51:51

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:53:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:53:32
Data point term sent to Coder	System	14 Oct 2020 16:53:14
User entered 'Symbicort'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'asthma'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '2'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'puff (PUFF)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'twice daily (BID)'	Meghan York (b) (4)	14 Oct 2020 16:52:43
	(b) (4)	

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2002'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:52:43

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:55:39
Data point term sent to Coder	System	14 Oct 2020 16:54:15
User entered 'Albuterol'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'asthma'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '2'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'puff (PUFF)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'as needed (PRN)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'un UNK 2002'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered '0'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered empty.	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:52:31
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:53:17

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:53:17

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
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 Dec 2020 20:07:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 20:07:51
Data point term sent to Coder	System	01 Dec 2020 20:06:25
User entered 'flu vaccine'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'flu prevention'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'unknown'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'Other (OTHER)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'unknown'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'once (ONCE)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered empty.	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'Intramuscular (INTRAMUSCULAR)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered empty.	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered '20 Oct 2020'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered '0'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered '20 Oct 2020'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:50:07
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User entered empty.	System	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User entered empty.	System	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:56:33
User entered empty.	System	01 Dec 2020 20:05:37

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:01:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:01:09
Data point term sent to Coder	System	21 Apr 2021 16:00:45
Coding entries removed.	Jill York (b) (4)	21 Apr 2021 16:00:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 17:33:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 17:33:56
Data point term sent to Coder	System	25 Jan 2021 17:32:27
User entered 'ELIQUIS'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:18
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 16:00:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 16:00:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Indication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:18
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 16:00:05
User entered 'STROKE PREVENTIon' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 16:00:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered 'stroke'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered '5'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered 'twice daily (BID)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:27:33
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 17:32:00
User entered '23 Nov 2020' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:32:00
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 17:31:56
User entered '23 Nov 2021'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered '0'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 03:13:07
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'subject is now taking this medication for stroke prevention ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 16:00:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		05 Mar 2021 17:35:22
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:52:29
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 17:32:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 17:32:03
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:32:03
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 17:31:56
User entered empty.	Meghan York (b) (4) (b) (4)	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 17:31:56

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 17:31:56

US3142161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:27:33

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:55:13
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	18 Mar 2021 20:50:39

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered '24 Feb 2021'	Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

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)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered 'subject received outside Moderna vaccine and withdrew consent at unblinding visit.'	Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered empty.	(b) (4) Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered empty.	Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:10:29
DataPoint Verified.		20 Apr 2021 15:57:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:29:32
User entered empty.	(b) (4) Jill York (b) (4)	06 Apr 2021 17:48:43

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Query 'Please provide source documentation pertaining to SAE. ' canceled (Site from CRA).		03 Mar 2021 19:19:29
User opened query 'Please provide source documentation pertaining to SAE. ' (Site from CRA).		03 Feb 2021 18:45:43
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'USA-US064-2021-MRNA-1273-P301000006'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
Query 'Please verify if hospital records have been requested.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:11:46
DataPoint Verified.		03 Mar 2021 19:19:40
User opened query 'Please verify if hospital records have been requested.' (Site from CRA).		03 Feb 2021 18:46:55
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093475

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093476

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Ripley'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093477

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Hollister'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '4190 East Woodmen Road Suite 210'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Colorado Springs'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '80920'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'US'	System	26 Jan 2021 14:35:18

FDA-CBER-2022-1614-0093482

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:09:24
User entered '2'	System	13 Apr 2021 13:58:15
User entered '1'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Query 'Please provide source documentation pertaining to SAE. ' canceled (Site from CRA).		03 Mar 2021 19:19:29
User opened query 'Please provide source documentation pertaining to SAE. ' (Site from CRA).		03 Feb 2021 18:45:43
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'USA-US064-2021-MRNA-1273-P301000006'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
Query 'Please verify if hospital records have been requested.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:11:46
DataPoint Verified.		03 Mar 2021 19:19:40
User opened query 'Please verify if hospital records have been requested.' (Site from CRA).		03 Feb 2021 18:46:55
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093486

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093490

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Ripley'	System	26 Jan 2021 14:35:03

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Hollister'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093493

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '4190 East Woodmen Road Suite 210'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093494

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Colorado Springs'	System	26 Jan 2021 14:35:03

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '80920'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093496

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'US'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:09:24
User entered '2'	System	13 Apr 2021 13:58:15
User entered '1'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:27:33

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
User entered '26/Jan/2021 09:35'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:27:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '1'		26 Jan 2021 14:35:18

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Query 'Please provide source documentation pertaining to SAE. ' canceled (Site from CRA).		03 Mar 2021 19:19:29
User opened query 'Please provide source documentation pertaining to SAE. ' (Site from CRA).		03 Feb 2021 18:45:43
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'USA-US064-2021-MRNA-1273-P301000006'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
Query 'Please verify if hospital records have been requested.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:11:46
DataPoint Verified.		03 Mar 2021 19:19:40
User opened query 'Please verify if hospital records have been requested.' (Site from CRA).		03 Feb 2021 18:46:55
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093502

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093504

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Ripley'	System	26 Jan 2021 14:35:03

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Hollister'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093510

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '4190 East Woodmen Road Suite 210'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Colorado Springs'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '80920'	System	26 Jan 2021 14:35:03

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'US'	System	26 Jan 2021 14:35:18

FDA-CBER-2022-1614-0093514

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:09:24
User entered '2'	System	13 Apr 2021 13:58:15
User entered '1'	System	26 Jan 2021 14:35:18

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:30:28
User entered '13/Apr/2021 09:58'	System	13 Apr 2021 13:58:15

FDA-CBER-2022-1614-0093516

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:27:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:30:28
Reviewed for Safety.		13 Apr 2021 16:09:12
User entered '1'		13 Apr 2021 13:58:15

FDA-CBER-2022-1614-0093517

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Query 'Please provide source documentation pertaining to SAE. ' canceled (Site from CRA).		03 Mar 2021 19:19:29
User opened query 'Please provide source documentation pertaining to SAE. ' (Site from CRA).		03 Feb 2021 18:45:43
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'USA-US064-2021-MRNA-1273-P301000006'	System	26 Jan 2021 14:35:03

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
Query 'Please verify if hospital records have been requested.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:11:46
DataPoint Verified.		03 Mar 2021 19:19:40
User opened query 'Please verify if hospital records have been requested.' (Site from CRA).		03 Feb 2021 18:46:55
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093519

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093520

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093521

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Yes (Y)'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'No (N)'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Ripley'	System	26 Jan 2021 14:35:03

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Hollister'	System	26 Jan 2021 14:35:03

FDA-CBER-2022-1614-0093527

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '4190 East Woodmen Road Suite 210'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'Colorado Springs'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered '80920'	System	26 Jan 2021 14:35:03

US3142161
Folder: SAE USA-US064-2021-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:27:33
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:19:40
Reviewed for Safety.		26 Jan 2021 14:35:25
User entered 'US'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 16:09:24
User entered '2'	System	13 Apr 2021 13:58:15
User entered '1'	System	26 Jan 2021 14:35:18

US3142161

Folder: SAE USA-US064-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:27:33

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:30:28
User entered '13/Apr/2021 12:09'	System	13 Apr 2021 16:09:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:42:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:30:28
User entered '1'		13 Apr 2021 16:09:24