US3272315 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272315

Form: Participant Creation

Data signed: [(b) (4)] **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Participant ID	US3272315

mRNA-1273-P301 Completion Guidelines

US3272315

Folder: Screening

Form: Visit Date

Data signed: (b) (4)   **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

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

| Visit date (dd MMM yyyy) | 23 AUG 2020 |

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

| Folder OID | SCRN |

US3272315

Folder: Screening

Form: Demographics

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	75
Age Units	YEARS
Age (Derived)	75
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

US3272315

Folder: Screening

Form: Enrollment

Data signed: ▒▒▒ (b) (4) ▒▒▒ **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Date of Informed Consent *(dd MMM yyyy)*	23 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

US3272315

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Did the participant meet all eligibility criteria?　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

US3272315

Folder: Screening

Form: Medical History Summary

Data signed: [(b) (4)] **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

Were any significant conditions reported?   Yes ●

                                                                No ◯

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4)　**09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3272315

Folder: Screening

Form: Medical History (2)

Data signed: [(b) (4)] **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	DIABETES MELLITUS (TYPE 2)
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3272315

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	SPINAL STENOSIS (LUMBAR REGION)
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3272315

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: Screening

Form: Medical History (5)

Data signed: [(b) (4)] **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3272315

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3272315

Folder: Screening

Form: Medical History (7)

Data signed: [(b) (4)] **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	BILATERAL OOPHORECOMY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3272315

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	CODEINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (9)

Data signed: [(b) (4)] **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4)   **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3272315

Folder: Screening

Form: Medical History (11)

Data signed: [redacted] (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

US3272315

Folder: Screening

Form: Vital Signs

Data signed: ▨▨▨ (b) (4) ▨▨▨ **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 AUG 2020
Time of assessment *(00:00-23:59)*	11:00 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 11:00
Height *(xxx.x)*	160.0 cm
Weight *(xxx.x)*	90.5 kg
BMI *(xxx.x)*	35.35156 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)	

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?	Yes ●
	No ○

Date of examination *(dd MMM yyyy)*   23 AUG 2020

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

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*	23 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 1986
Date of last menstruation unknown	False

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: Screening

Form: Risk of Exposure

Data signed: [(b) (4)] **09 Apr 2021 15:11:05**

Generated On: 09 Jun 2021 16:28:14

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	

US3272315

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	23 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

What was the date of randomization? *(dd MMM yyyy)*	23 AUG 2020
What was the participant's randomization number?	187851

In what Cohort was the participant enrolled?

- ○ >=18 and <65 years and not at risk
- ○ >=18 and <65 years and at risk
- ● >=65 years

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○ No ●
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○ No ●
Severe obesity (body mass index > or = 40kg/m2)	Yes ○ No ●
Diabetes (Type I, Type 2, or gestational)	Yes ● No ○
Liver Disease	Yes ○ No ●
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Height	ND - Not Done
Weight	ND - Not Done

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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)*	23 AUG 2020
Time of assessment *(00:00-23:59)*	11:00 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 11:00
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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)*	23 AUG 2020
Time of assessment *(00:00-23:59)*	12:54 (24 HR)
Vital Signs Date and Time (derived)	23 AUG 2020 12:54
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	_____
Pulse *(xxx)*	93 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed? Yes ● No ○

Date of examination *(dd MMM yyyy)* 23 AUG 2020

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

Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

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)*	23 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:12 (24 HR)
Treatment Date and Time (derived)	23 AUG 2020 12:12
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	23 AUG 2020
Collection time *(00:00-23:59)*	11:30 (24 HR)
Collection date and time (derived)	23 AUG 2020 11:30

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*			23 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:27	23 AUG 2020 11:27
Nasopharyngeal Swab 2	No		

US3272315

Folder: Visit 1 Day 1

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 AUG 2020 12:56
PC Open Date & Time	23 AUG 2020 12:32
PC Close Date & Time	23 AUG 2020 15:02

FDA-CBER-2022-1614-1648025

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

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**	98.8 °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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 AUG 2020 16:39
PC Open Date & Time	23 AUG 2020 15:57
PC Close Date & Time	24 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	24 AUG 2020 12:20
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 AUG 2020 14:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-1648028

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

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**	98.1 °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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	26 AUG 2020 15:04
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	27 AUG 2020 12:32
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-1648030

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	28 AUG 2020 15:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-1648031

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-1648032

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 8

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	30 AUG 2020 14:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 9

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	31 AUG 2020 15:58
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-1648034

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 10

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	01 SEP 2020 15:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 11

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	02 SEP 2020 13:51
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-1648036

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 12**

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	03 SEP 2020 14:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 13

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	05 SEP 2020 00:29
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 14

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	06 SEP 2020 00:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 15

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	06 SEP 2020 16:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 16

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	08 SEP 2020 01:20
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 17

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	08 SEP 2020 18:24
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 18

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	10 SEP 2020 00:10
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 19

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 SEP 2020 00:04
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 20

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 SEP 2020 17:48
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-1648045

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 21

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	12 SEP 2020 20:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-1648046

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 22

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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	13 SEP 2020 19:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 23

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	14 SEP 2020 21:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 24

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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	15 SEP 2020 13:58
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-1648049

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 25

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 SEP 2020 15:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-1648050

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 26

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	99.1 °F

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

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	17 SEP 2020 13:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14

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.

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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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 SEP 2020 17:59
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-1648052

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 28

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	20 SEP 2020 00:00
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 29

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	21 SEP 2020 00:19
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

TIMEPOINT	DAY 30

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.

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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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	22 SEP 2020 00:36
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 31

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

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

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

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

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

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

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-1648056

TIMEPOINT	DAY 32

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 SEP 2020 14:55
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-1648057

TIMEPOINT	DAY 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**	98.0 °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):

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	24 SEP 2020 23:02
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 34

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 18:17
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

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	23 AUG 2020 12:52
PC Open Date & Time	23 AUG 2020 12:32
PC Close Date & Time	23 AUG 2020 15:02

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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	23 AUG 2020 16:40
PC Open Date & Time	23 AUG 2020 15:57
PC Close Date & Time	24 AUG 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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.	3

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	24 AUG 2020 12:18
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

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	25 AUG 2020 14:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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	26 AUG 2020 15:05
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 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	27 AUG 2020 12:33
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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	28 AUG 2020 15:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

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 ◯

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	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

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 ○

Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

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

PC Time stamp	23 AUG 2020 12:54
PC Open Date & Time	23 AUG 2020 12:32
PC Close Date & Time	23 AUG 2020 15:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

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 ○

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	23 AUG 2020 16:41
PC Open Date & Time	23 AUG 2020 15:57
PC Close Date & Time	24 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14

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	24 AUG 2020 12:20
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14

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	25 AUG 2020 14:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14

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	26 AUG 2020 15:05
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14

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	27 AUG 2020 12:33
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14

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	28 AUG 2020 15:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3272315

Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14

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	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ⭕
PC Time stamp	30 AUG 2020 14:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	31 AUG 2020 15:58
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	01 SEP 2020 15:10
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	02 SEP 2020 13:52
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ◯
PC Time stamp	03 SEP 2020 14:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	05 SEP 2020 00:30
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	06 SEP 2020 00:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 15
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	06 SEP 2020 16:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	08 SEP 2020 01:20
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	08 SEP 2020 18:25
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	10 SEP 2020 00:10
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	11 SEP 2020 00:04
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 20
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	11 SEP 2020 17:48
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	12 SEP 2020 20:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 22
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	13 SEP 2020 19:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 23
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	14 SEP 2020 21:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 24
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	15 SEP 2020 13:59
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 25
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	16 SEP 2020 15:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 26
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	17 SEP 2020 13:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 27
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	18 SEP 2020 18:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 28
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	20 SEP 2020 00:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 29
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	21 SEP 2020 00:19
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	22 SEP 2020 00:36
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 31
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯ Yes ◯
PC Time stamp	
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(32)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 32
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	23 SEP 2020 14:55
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	24 SEP 2020 23:02
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(34)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 34
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	25 SEP 2020 18:17
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3272315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

| 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 _____

US3272315

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: ▨ (b) (4) ▨ **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                     No ◯

Continuing Flag   1

US3272315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3272315

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                     No ◯

Continuing Flag   1

US3272315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 14 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag	1

US3272315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT2

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: [(b) (4)] **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	26 SEP 2020
Time of assessment *(00:00-23:59)*	11:11 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 11:11
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	98 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1648118

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Timepoint	Pre-Dose ⬭
	Post-Dose ⬛
Were vital signs assessed?	Yes ⬛
	No ⬭
Date of assessment *(dd MMM yyyy)*	26 SEP 2020
Time of assessment *(00:00-23:59)*	12:35 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:35
Temperature *(xxx.x)*	37.3 C
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	91 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?	Yes ⬤
	No ◯

Date of examination *(dd MMM yyyy)*   26 SEP 2020

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)*	26 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:04 (24 HR)
Treatment Date and Time (derived)	26 SEP 2020 12:04
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

US3272315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?	Yes ●
	No ◯
Collection date *(dd MMM yyyy)*	26 SEP 2020
Collection time *(00:00-23:59)*	11:30 (24 HR)
Collection date and time (derived)	26 SEP 2020 11:30

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)* 26 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:22	26 SEP 2020 11:22
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1648123

US3272315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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**	99.3 °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	26 SEP 2020 12:35
PC Open Date & Time	26 SEP 2020 12:24
PC Close Date & Time	26 SEP 2020 14:54

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**	98.5 °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	27 SEP 2020 10:13
PC Open Date & Time	26 SEP 2020 15:49
PC Close Date & Time	27 SEP 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯

Please record your **TEMPERATURE in °F**	98.5 °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	27 SEP 2020 18:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

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US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 SEP 2020 22:08
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.1 °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	30 SEP 2020 21:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.2 °F

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

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

PC Time Stamp	02 OCT 2020 02:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

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

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

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

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

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

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-1648132

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

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	26 SEP 2020 12:37
PC Open Date & Time	26 SEP 2020 12:24
PC Close Date & Time	26 SEP 2020 14:54

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

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.	1
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	27 SEP 2020 10:15
PC Open Date & Time	26 SEP 2020 15:49
PC Close Date & Time	27 SEP 2020 11:59

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	27 SEP 2020 18:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

| Is there any **REDNESS AT INJECTION SITE**? | Yes ◯ |
| | No ◯ |

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

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

| Is there any **SWELLING/HARDNESS AT INJECTION SITE**? | Yes ◯ |
| | No ◯ |

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ◯
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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	29 SEP 2020 22:08
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 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	30 SEP 2020 21:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

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	02 OCT 2020 02:04
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 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 ◯

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	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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	◯

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	26 SEP 2020 12:39
PC Open Date & Time	26 SEP 2020 12:24
PC Close Date & Time	26 SEP 2020 14:54

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

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	27 SEP 2020 10:15
PC Open Date & Time	26 SEP 2020 15:49
PC Close Date & Time	27 SEP 2020 11:59

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 ●

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	Yes ◯
PC Time stamp	27 SEP 2020 18:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14

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	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14

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	29 SEP 2020 22:09
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-1648150

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14

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	30 SEP 2020 21:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14

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	02 OCT 2020 02:05
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 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	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3272315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	05 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3272315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ⬤

                                                                     No ◯

Continuing Flag   1

US3272315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3272315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: [(b) (4)] **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	22 OCT 2020
Time of assessment *(00:00-23:59)*	13:24 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:24
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-1648164

US3272315

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4)   **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

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.

US3272315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

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

Collection date *(dd MMM yyyy)*	22 OCT 2020
Collection time *(00:00-23:59)*	13:33 (24 HR)
Collection date and time (derived)	22 OCT 2020 13:33

US3272315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	23 OCT 2020 00:02:20
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	06 NOV 2020 10:30:55
Patient Cloud Open Date & Time	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-1648172

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 21:57:26
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 03:34:12
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 08:00:33
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	18 DEC 2020 16:35:06
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	22 DEC 2020 12:26:12
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	02 JAN 2021 04:24:37
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 01:02:17
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	15 JAN 2021 20:57:31
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	19 JAN 2021 01:44:01
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	26 JAN 2021 00:02:25
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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	05 FEB 2021 18:12:03
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

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US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 ○
Have 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)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ●
Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 FEB 2021 12:20:44
Patient Cloud Open Date & Time	09 FEB 2021 00:01

PRODUCTION RELEASE (v12.003 EAB) (1725)

Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 17:13:18
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 12:02:50
Patient Cloud Open Date & Time	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 ≥ 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-2022-1614-1648191

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 14:09:38
Patient Cloud Open Date & Time	09 MAR 2021 00:01
Patient Cloud Close Date & Time	13 MAR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 00:01:52
Patient Cloud Open Date & Time	16 MAR 2021 00:01
Patient Cloud Close Date & Time	20 MAR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 00:01:59
Patient Cloud Open Date & Time	23 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ●
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have 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	03 APR 2021 09:00:04
Patient Cloud Open Date & Time	30 MAR 2021 00:01
Patient Cloud Close Date & Time	03 APR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 12:38:16
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 16:29:43
Patient Cloud Open Date & Time	13 APR 2021 00:01
Patient Cloud Close Date & Time	17 APR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 12:00:39
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 APR 2021 00:01:38
Patient Cloud Open Date & Time	27 APR 2021 00:01
Patient Cloud Close Date & Time	01 MAY 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 257**

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

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

Fever (Temperature ≥ 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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 MAY 2021 00:01
Patient Cloud Close Date & Time	08 MAY 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 264**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 MAY 2021 00:01
Patient Cloud Close Date & Time	15 MAY 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   **DAY 271**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 MAY 2021 00:01
Patient Cloud Close Date & Time	22 MAY 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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):

Symptom	
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 ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 MAY 2021 00:01
Patient Cloud Close Date & Time	29 MAY 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 285**

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

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 292**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	12 JUN 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 299**

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

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

Fever (Temperature ≥ 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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 306**

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 313

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2021 00:01
Patient Cloud Close Date & Time	03 JUL 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   DAY 320

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2021 00:01
Patient Cloud Close Date & Time	10 JUL 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 327**

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

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

Fever (Temperature $\geq$ 100.4°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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2021 00:01
Patient Cloud Close Date & Time	17 JUL 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 334**

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

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

Symptom	
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 ⃝

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US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2021 00:01
Patient Cloud Close Date & Time	24 JUL 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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-2022-1614-1648225

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2021 00:01
Patient Cloud Close Date & Time	31 JUL 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-1648227

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 AUG 2021 00:01
Patient Cloud Close Date & Time	07 AUG 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 355**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2021 00:01
Patient Cloud Close Date & Time	14 AUG 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 362

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-1648231

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 AUG 2021 00:01
Patient Cloud Close Date & Time	21 AUG 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 369**

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-1648233

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 AUG 2021 00:01
Patient Cloud Close Date & Time	28 AUG 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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-2022-1614-1648235

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 AUG 2021 00:01
Patient Cloud Close Date & Time	04 SEP 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 383

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

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

Fever (Temperature ≥ 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 ◯

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2021 00:01
Patient Cloud Close Date & Time	11 SEP 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 390**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2021 00:01
Patient Cloud Close Date & Time	18 SEP 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 397

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

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

Fever (Temperature ≥ 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-2022-1614-1648241

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2021 00:01
Patient Cloud Close Date & Time	25 SEP 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 404**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2021 00:01
Patient Cloud Close Date & Time	02 OCT 2021 23:59

TIMEPOINT   DAY 411

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

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

Symptom	
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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2021 00:01
Patient Cloud Close Date & Time	09 OCT 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 418

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

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

Fever (Temperature ≥ 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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2021 00:01
Patient Cloud Close Date & Time	16 OCT 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 425

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

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

Fever (Temperature ≥ 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-2022-1614-1648249

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 432**

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

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

Symptom	
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-2022-1614-1648251

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2021 00:01
Patient Cloud Close Date & Time	30 OCT 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 439

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

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

Fever (Temperature ≥ 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-2022-1614-1648253

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 NOV 2021 00:01
Patient Cloud Close Date & Time	06 NOV 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT **DAY 446**

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

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 NOV 2021 00:01
Patient Cloud Close Date & Time	13 NOV 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 453

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2021 00:01
Patient Cloud Close Date & Time	20 NOV 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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):

Symptom	
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 ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 NOV 2021 00:01
Patient Cloud Close Date & Time	27 NOV 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT **DAY 467**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-1648261

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 NOV 2021 00:01
Patient Cloud Close Date & Time	04 DEC 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 481**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

DAY 488

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Date and time of submission	
Patient Cloud Open Date & Time	21 DEC 2021 00:01
Patient Cloud Close Date & Time	25 DEC 2021 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 495**

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

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

Fever (Temperature ≥ 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-2022-1614-1648269

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 DEC 2021 00:01
Patient Cloud Close Date & Time	01 JAN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 502

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-1648271

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 JAN 2022 00:01
Patient Cloud Close Date & Time	08 JAN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   DAY 509

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

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

Fever (Temperature ≥ 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-2022-1614-1648273

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 JAN 2022 00:01
Patient Cloud Close Date & Time	15 JAN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   **DAY 516**

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

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

Symptom	
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 ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 JAN 2022 00:01
Patient Cloud Close Date & Time	22 JAN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 523**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 JAN 2022 00:01
Patient Cloud Close Date & Time	29 JAN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 530**

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

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

Fever (Temperature ≥ 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 ⚪

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	05 FEB 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 537

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

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

Fever (Temperature ≥ 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 ⚪

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	12 FEB 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 544**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	19 FEB 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 551

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 558**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Symptom	
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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	05 MAR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 565**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-1648289

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	12 MAR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   DAY 572

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

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

Fever (Temperature ≥ 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-2022-1614-1648291

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 MAR 2022 00:01
Patient Cloud Close Date & Time	19 MAR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 586**

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

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

Fever (Temperature ≥ 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 ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	29 MAR 2022 00:01
Patient Cloud Close Date & Time	02 APR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   DAY 593

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

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 APR 2022 00:01
Patient Cloud Close Date & Time	09 APR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 600**

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 APR 2022 00:01
Patient Cloud Close Date & Time	16 APR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 607**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 614**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 APR 2022 00:01
Patient Cloud Close Date & Time	30 APR 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 621**

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

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

Symptom	
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 ○

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	03 MAY 2022 00:01
Patient Cloud Close Date & Time	07 MAY 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 628

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

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

Symptom	
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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 MAY 2022 00:01
Patient Cloud Close Date & Time	14 MAY 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 MAY 2022 00:01
Patient Cloud Close Date & Time	21 MAY 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 642

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 MAY 2022 00:01
Patient Cloud Close Date & Time	28 MAY 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 649**

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

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 MAY 2022 00:01
Patient Cloud Close Date & Time	04 JUN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 656**

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

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

Fever (Temperature ≥ 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 ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 JUN 2022 00:01
Patient Cloud Close Date & Time	11 JUN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 663**

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

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 JUN 2022 00:01
Patient Cloud Close Date & Time	18 JUN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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):

Symptom	
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 ◯

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2022 00:01
Patient Cloud Close Date & Time	25 JUN 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 677**

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

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

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

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

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

Symptom	
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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUN 2022 00:01
Patient Cloud Close Date & Time	02 JUL 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 684

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-1648323

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2022 00:01
Patient Cloud Close Date & Time	09 JUL 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 691**

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

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-1648325

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2022 00:01
Patient Cloud Close Date & Time	16 JUL 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2022 00:01
Patient Cloud Close Date & Time	23 JUL 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 705**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-1648329

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2022 00:01
Patient Cloud Close Date & Time	30 JUL 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 712**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 AUG 2022 00:01
Patient Cloud Close Date & Time	06 AUG 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 719**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 AUG 2022 00:01
Patient Cloud Close Date & Time	13 AUG 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 726

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2022 00:01
Patient Cloud Close Date & Time	20 AUG 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 733**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 AUG 2022 00:01
Patient Cloud Close Date & Time	27 AUG 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 740

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 AUG 2022 00:01
Patient Cloud Close Date & Time	03 SEP 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 747**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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 ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2022 00:01
Patient Cloud Close Date & Time	10 SEP 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	**DAY 754**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2022 00:01
Patient Cloud Close Date & Time	17 SEP 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 761

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

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

Symptom	
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 ◯

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 SEP 2022 00:01
Patient Cloud Close Date & Time	24 SEP 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 768

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

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

Symptom	
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-2022-1614-1648347

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 SEP 2022 00:01
Patient Cloud Close Date & Time	01 OCT 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 775

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 OCT 2022 00:01
Patient Cloud Close Date & Time	08 OCT 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2022 00:01
Patient Cloud Close Date & Time	15 OCT 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT   DAY 789

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

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

Fever (Temperature ≥ 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 ◯

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2022 00:01
Patient Cloud Close Date & Time	22 OCT 2022 23:59

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT DAY 796

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-1648355

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2022 00:01
Patient Cloud Close Date & Time	29 OCT 2022 23:59

US3272315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:28:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission	
No		12 MAR 2021 14:08:42	

US3272315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?   Yes ●

No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   18 NOV 2020

Please select one status for the follow-up contact   Contact Made ●

Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                          No ○

Continuing Flag   1

US3272315

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

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

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

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3272315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 22 JAN 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                   No ◯

Continuing Flag   1

US3272315
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4)   **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 FEB 2021 |

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

Comments

If Contact Not Made, please provide Comments _____

US3272315

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3272315

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4)   **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT4

US3272315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: [(b) (4)] **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

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) _____

US3272315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4)　　**29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Date of examination *(dd MMM yyyy)*　　　　　　　　12 MAR 2021

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

US3272315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	12 MAR 2021
Collection time *(00:00-23:59)*	13:45 (24 HR)
Collection date and time (derived)	12 MAR 2021 13:45

US3272315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4)   **29 Apr 2021 23:47:29**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                                                                No ○

Continuing Flag   1

Data signed: (b) (4) **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-1648371

US3272315

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3272315
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted? Yes ◯

No ◯

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

Please select one status for the follow-up contact Contact Made ◯

Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag   _____

US3272315
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:28:14

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 ◯

Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 16:28:14

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3272315

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

Form: Visit Date

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	08 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	08 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	08 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3272315

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

US3272315

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	08 JAN 2021
Time of assessment *(00:00-23:59)*	13:55 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 13:55
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ⚪
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⚪
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 15:01
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ⬤
	Axillary ⚪
	Other ⚪
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Physical Examination

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?	Yes ●
	No ○

Date of examination *(dd MMM yyyy)*	08 JAN 2021

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	08 JAN 2021
What was the treatment time? *(00:00-23:59)*	14:29 (24 HR)
Treatment Date and Time (derived)	08 JAN 2021 14:29

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

FDA-CBER-2022-1614-1648383

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?	Yes	●
	No	○

Collection date *(dd MMM yyyy)*	08 JAN 2021
Collection time *(00:00-23:59)*	13:34 (24 HR)
Collection date and time (derived)	08 JAN 2021 13:34

US3272315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	08 JAN 2021
Collection time *(00:00 - 23:59)*	13:38
Collection Date and Time (derived)	08 JAN 2021 13:38

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3272315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: ▨ (b) (4) ▨ **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3272315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag	1
OLD29 Placebo Flag	1

US3272315
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	04 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●

Folder OID	OLD29

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	04 FEB 2021
Time of assessment *(00:00-23:59)*	10:55 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:55
Temperature *(xxx.x)*	37.0 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Timepoint	Pre-Dose ⭘
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭘
Date of assessment *(dd MMM yyyy)*	04 FEB 2021
Time of assessment *(00:00-23:59)*	12:26 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 12:26
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ⭘
	Other ⭘
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3272315

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?   Yes ●

                                                            No ○

Date of examination *(dd MMM yyyy)*   04 FEB 2021

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

US3272315

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was study treatment given?	Yes ●
	No ○

If No, reason not given	
Participant declined due to Adverse Event	○
Physician withheld dose due to Adverse Event	○
Death	○
Lost To Follow-Up	○
Physician Decision	○
Pregnancy	○
Protocol Deviation	○
Study Terminated by Sponsor	○
Withdrawal of Consent by Participant	○
Confirmed COVID-19	○
Other	○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	04 FEB 2021
What was the treatment time? *(00:00-23:59)*	11:51 (24 HR)
Treatment Date and Time (derived)	04 FEB 2021 11:51
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

US3272315

Folder: OL-D29 (1)

Form: Continuing

Data signed: ▨ (b) (4) ▨ **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit? Yes ⬤

                    No ◯

Continuing Flag 1

US3272315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3272315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

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

Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | OLD57 |

FDA-CBER-2022-1614-1648397

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: [(b) (4)] **29 Apr 2021 23:47:53**
Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 MAR 2021
Time of assessment *(00:00-23:59)*	13:31 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 13:31
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	98 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-1648398

US3272315

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?   Yes ●

                                                                                  No ○

Date of examination *(dd MMM yyyy)*   12 MAR 2021

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)*	12 MAR 2021
Collection time *(00:00-23:59)*	13:45 (24 HR)
Collection date and time (derived)	12 MAR 2021 13:45

US3272315

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **09 Apr 2021 15:11:04**

Generated On: 09 Jun 2021 16:28:14

Did the participant experience any adverse events?   Yes ●

                                                                                     No ○

If Yes, enter details on the Adverse Events form.

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: ██████ (b) (4) ██████ **03 May 2021 16:59:37**

Generated On: 09 Jun 2021 16:28:14

AEID	
Adverse event	BILATERAL SEROUS OTITIS - EARS.
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)*	5 FEB 2021
Start time *(00:00-23:59)*	00:01 (24 HR)
AE start date and time (derived)	5 FEB 2021 00:01
Ongoing?	Yes ◯
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	06 MAR 2021
End time *(00:00-23:59)*	00:01 (24 HR)
AE End Date and Time (derived)	06 MAR 2021 00:01
Severity	Grade 1/Mild ●
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯

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FDA-CBER-2022-1614-1648402

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **03 May 2021 16:59:37**

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: [(b) (4)] **03 May 2021 16:59:37**

Generated On: 09 Jun 2021 16:28:14

AEID	
Adverse event	SINUSITIS
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)*	08 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	06 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ⬤
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

FDA-CBER-2022-1614-1648405

SUBJECT WAS SEEN BY PCP ON 08FEB2021 DUE TO NASAL CONGESTION AND COUGH DUE TO THE DRAINAGE. SHE ALSO COMPLAINS OF EARS FEELING FULL. SHE WAS GIVEN ANTIBIOTICS DUE TO DIAGNOSIS OF SINUSITIS AND ACUTE SEROUS OTITIS MEDIA BILATERALLY.

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

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: [(b) (4)] **03 May 2021 16:59:37**

Generated On: 09 Jun 2021 16:28:14

AEID	USA-US070-2021-MRNA-1273-P30 1000010
Adverse event	AORTIC STENOSIS
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)*	01 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	31 MAR 2021
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	29 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	01 APR 2021
Admitted to ICU?	Yes ○
	No ●
	Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

Not Related ⬤
Related ◯
Not Applicable ◯

Relationship to Study Procedure

Not Related ⬤
Related ◯
Not Applicable ◯

Action taken with investigational product

None ⬤
Dose Delayed ◯
Investigational Product Withdrawn ◯
Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FDA-CBER-2022-1614-1648408

SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN.

(b) (6)

A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND

WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.

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

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: [blank] (b) (4) [blank] **03 May 2021 16:59:37**

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AEID	
Adverse event	WORSENING OF AORTIC STENOSIS
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)*	01 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	31 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

Not Related	⬤
Related	◯
Not Applicable	◯

Relationship to Study Procedure

Not Related	⬤
Related	◯
Not Applicable	◯

Action taken with investigational product

None	◯
Dose Delayed	◯
Investigational Product Withdrawn	◯
Not Applicable	⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

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 HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING ▨ (b) (6) ▨ AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN.

▨ (b) (6) ▨

A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND

WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.

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

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Form: Adverse Events (5)

Data signed: (b) (4) **03 May 2021 16:59:37**

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AEID	
Adverse event	SYNCOPE
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)*	01 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⭕
	No ⚫
If not Ongoing, end date *(dd MMM yyyy)*	01 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⭕
	Grade 2/Moderate ⭕
	Grade 3/Severe ⚫
	Grade 4 ⭕
Is the adverse event serious?	Yes ⭕
	No ⚫
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ⭕
	No ⭕
	Unknown ⭕
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	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

FDA-CBER-2022-1614-1648416

SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN.

(b) (6)

A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND

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	WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Form: Adverse Events (6)

Data signed: [(b) (4)] **03 May 2021 16:59:37**

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AEID	
Adverse event	EXERCISE INTOLERANCE
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)*	15 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	04 APR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: ▇▇▇ (b) (4) ▇▇▇ **03 May 2021 16:59:37**

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AEID	
Adverse event	BILATERAL LOWER EXTREMITY EDEMA

| 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)*	15 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

| Ongoing? | Yes ◯ |
| | No ⬤ |

If not Ongoing, end date *(dd MMM yyyy)*	03 APR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

| Is the adverse event serious? | Yes ◯ |
| | No ⬤ |

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯

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Form: Adverse Events (7)

Data signed: (b) (4) **03 May 2021 16:59:37**

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Form: Adverse Events (8)

Data signed: ░░░ (b) (4) ░░░ **03 May 2021 16:59:37**

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AEID	USA-US070-2021-MRNA-1273-P30 1000010
Adverse event	REDUCED EJECTION FRACTION HEART FAILURE

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)*	15 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ○　　No ●

If not Ongoing, end date *(dd MMM yyyy)*	03 MAR 2021
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	29 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	01 APR 2021

Admitted to ICU?　　Yes ○　　No ●　　Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FDA-CBER-2022-1614-1648424

SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN.

(b) (6)

A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND

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WOKE UP A FEW MINUTES
LATER. DID NOT SEEK
MEDICAL ATTENTION AT THAT
TIME DUE TO BEING OUT OF
TOWN, MADE F/U THE NEXT
WEEK WITH ECHO. ECHO
REVEALED SEVERE AORTIC
STENOSIS AND EF 10%,
REFERRED TO CARDIOLOGY.
LEFT HEART
CATHETERIZATION 29MAR2021
REVEALED NO BLOCKAGES.
TAVR 31MAR2021 WITH
RESOLUTION OF SYMPTOMS.
ATTENDING CARDIAC REHAB.
REQUESTING RECORDS FROM
HOSPITAL, SUBJECT AGREES.

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

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AEID	
Adverse event	SHORTNESS OF BREATH
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)*	15 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	31 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

FDA-CBER-2022-1614-1648428

SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. (b) (6)

A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND

WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: [b) (4)] **03 May 2021 16:59:37**

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AEID	
Adverse event	SERIOUS OTITIS MEDIA BILATERALLY

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)*	05 FEB 2021
Start time *(00:00-23:59)*	09:00 (24 HR)
AE start date and time (derived)	05 FEB 2021 09:00

Ongoing?	Yes	○
	No	●

If not Ongoing, end date *(dd MMM yyyy)*	06 MAR 2021
End time *(00:00-23:59)*	21:00 (24 HR)
AE End Date and Time (derived)	06 MAR 2021 21:00

Severity	Grade 1/Mild	●
	Grade 2/Moderate	○
	Grade 3/Severe	○
	Grade 4	○
Is the adverse event serious?	Yes	○
	No	●

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?	Yes	○
	No	○
	Unknown	○

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: [(b) (4)] **03 May 2021 16:59:37**

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AEID	
Adverse event	SHORTNESS OF BREATH
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)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	15 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯

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

Other action taken (check all that apply)

None	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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Form: Adverse Events (12)

Data signed: [(b) (4)] **03 May 2021 16:59:37**

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AEID	
Adverse event	EDEMA, BILATERAL TOES, RIGHT HAND, 4TH FINGER

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)*	12 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○

No ●

If not Ongoing, end date *(dd MMM yyyy)*	15 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ●

Grade 2/Moderate ○

Grade 3/Severe ○

Grade 4 ○

Is the adverse event serious?   Yes ○

No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?   Yes ○

No ○

Unknown ○

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) **03 May 2021 16:59:37**

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

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: [(b) (4)] **09 Apr 2021 15:11:04**

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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)   **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	LEVOTHYROXINE

Prophylaxis	Yes ⚪
	No ⚫

Indication	HYPOTHYROIDISM
Dose per administration	25

Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚫

If dose unit is Other, specify	MCG

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 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: [(b) (4)] **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	METFORMIN

Prophylaxis

Yes ○
No ⬤

Indication	DIABETES MELLITUS (TYPE 2)
Dose per administration	500

Dose unit

mg ⬤
ug ○
mL ○
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

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EAB) (1725)

US3272315

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **29 Apr 2021 23:47:52**
Generated On: 09 Jun 2021 16:28:14

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 2000
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 (3)

Data signed: [(b) (4)] **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	GLIPIZIDE
Prophylaxis	Yes ⦿
	No ●
Indication	DIABETES MELLITUS (TYPE 2)
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 ⦿

	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 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	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 (4)

Data signed: [(b) (4)] **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	MELOXICAM
Prophylaxis	Yes ◯
	No ⬤
Indication	SPINAL STENOSIS (LUMBAR REGION)
Dose per administration	7.5
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	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 (5)

Data signed: ▢ (b) (4) ▢ **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	FLEXERIL

Prophylaxis

Yes ◯
No ⬤

Indication	SPINAL STENOSIS (LUMBAR REGION)
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

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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 2017
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4)   **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	LISINOPRIL
Prophylaxis	Yes ⬭
	No ⬤
Indication	HYPERLIPIDEMIA
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 ⬭

	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 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	SIMVASTATIN

Prophylaxis

- Yes ◯
- No ⬤

Indication	HYPERLIPIDEMIA
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 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	TYLENOL
Prophylaxis	Yes ○
	No ⬤
Indication	SPINAL STENOSIS (LUMBAR REGION)
Dose per administration	500
Dose unit	mg ⬤
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ⬤
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ○
	Subcutaneous ○
	Transdermal ○

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

If route of administration is Other, specify

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

Start date completely unknown — False

Ongoing? — Yes ⬤ / No ◯

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

Was this medication taken for solicited event? — Yes ◯ / No ⬤

Separate Dosage Number (derived) — 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 (9)

Data signed: [(b) (4)] **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	PRILOSEC
Prophylaxis	Yes ⚪
	No ⚫
Indication	GASTROESOPHAGEAL REFLUX DISEASE
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 1990
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 (10)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	PREDNISONE

Prophylaxis	Yes ⭘
	No ⬤

Indication	SINUSITIS AND SOM BILATERALLY

Dose per administration	30

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 ⭘

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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)*	8 FEB 2021
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 (11)

Data signed: (b) (4)   **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	DOXYCYCLINE

Prophylaxis	Yes ⭕
	No ⬤

Indication	SINUSITIS AND SOM BILATERALLY

Dose per administration	100

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 ⭕

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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)*	8 FEB 2021
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 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	INFLUENZA VACCINE

Prophylaxis	Yes ●
	No ◯

Indication	INFLUENZA PROPHYLAXIS

Dose per administration	0.5

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4)   **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	LASIX

Prophylaxis	Yes ◯
	No ⬤

Indication	WORSENING OF AORTIC STENOSIS

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 ◯

FDA-CBER-2022-1614-1648462

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)*	19 MAR 2021
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 (14)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

Name of Medication	ASPIRIN

Prophylaxis

- Yes ○
- No ●

Indication	CARDIAC HEALTH
Dose per administration	UNK

Dose unit

- mg ○
- ug ○
- mL ○
- g ○
- IU ○
- tablet ○
- capsule ○
- puff ○
- Other ●

If dose unit is Other, specify	UNK

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)*	01 APR 2021
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 (15)

Data signed: (b) (4) **29 Apr 2021 23:47:52**

Generated On: 09 Jun 2021 16:28:14

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 APR 2021
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 ⬤

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: [(b) (4)] **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Were any concomitant procedures performed?   Yes ⬤

                                                            No ◯

If yes, please complete Concomitant Procedures form.

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **29 Apr 2021 23:47:53**

Generated On: 09 Jun 2021 16:28:14

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
31 MAR 2021	TRANSCATHETER AORTIC VALVE REPLACEMENT	Adverse Event	
29 MAR 2021	LEFT HEART CATHETERIZATION	Adverse Event	

US3272315
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 16:28:14

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 _____

Date of study discontinuation/completion *(dd MMM yyyy)* _____

Reason for discontinuation	
AE (specify)	◯
SAE (specify)	◯
Complete	◯
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Other	◯

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

If reason for discontinuation is Death, main cause of death	
Adverse event	◯
Unknown	◯
Other	◯

If main cause of death is Other, specify _____

Date of death *(dd MMM yyyy)* _____

Was autopsy performed?	
Yes	◯
No	◯
Unknown	◯

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: ███ (b) (4) ███ **03 May 2021 16:59:38**

Generated On: 09 Jun 2021 16:28:14

SAEID	USA-US070-2021-MRNA-1273-P30 1000010
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: [(b) (4)] **03 May 2021 16:59:38**

Generated On: 09 Jun 2021 16:28:14

SAEID	USA-US070-2021-MRNA-1273-P30 1000010
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 11:32
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

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) **03 May 2021 16:59:38**

Generated On: 09 Jun 2021 16:28:14

SAEID	USA-US070-2021-MRNA-1273-P30 1000010
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 06:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: [(b) (4)] **03 May 2021 16:59:38**

Generated On: 09 Jun 2021 16:28:14

SAEID	USA-US070-2021-MRNA-1273-P30 1000010
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/APR/2021 15:38
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

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: ☐ (b) (4) **03 May 2021 16:59:38**

Generated On: 09 Jun 2021 16:28:14

SAEID	USA-US070-2021-MRNA-1273-P30 1000010
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAY/2021 05:55
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

US3272315 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272315

Form: Participant Creation

Generated On: 09 Jun 2021 16:28:14

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'US3272315'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:12

US3272315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:04

US3272315
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '23 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:13

US3272315

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

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 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:04

US3272315
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'SCRN'	System	23 Aug 2020 17:31:04

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:13

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '75'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:28:14
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'YEARS'	System	23 Aug 2020 17:31:14

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:28:14

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '75'	System	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Female (F)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:28:14
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '1'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:14

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	23 Aug 2020 17:31:14

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '23 Aug 2020'	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Aug 2020'	System	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2020'	System	23 Aug 2020 17:31:36

US3272315
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:28:14
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Amendment 2 (2)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:36

US3272315

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:14

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:13

US3272315
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:28:14
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1'	System	23 Aug 2020 17:31:41

US3272315

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:28:14

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Ashley Bell (b) (4)	23 Aug 2020 17:31:41

Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:28:14

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:28:14

FDA-CBER-2022-1614-1648509

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:29
Data point term sent to Coder	System	25 Aug 2020 15:28:56
User entered 'hypothyroidism'	(b) (4), (b) (6)	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:28:33

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 2018'	System	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2018'	System	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:28:33

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:28
Data point term sent to Coder	System	25 Aug 2020 15:28:56
User entered 'diabetes mellitus (type 2)'	(b) (4), (b) (6)	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 15:28:47

US3272315
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:28:14
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:28:47

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1990'	System	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1990'	System	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:28:47

US3272315
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:28:14
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:28:47

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Lumbar spinal stenosis, LLT: Spinal stenosis of lumbar region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:22:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:22:16
Data point term sent to Coder	System	17 Nov 2020 18:07:20
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 18:06:47
User entered 'SPINAL STENOSIS (lumbar region)' reason for change: Data Entry Error		17 Nov 2020 18:06:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:29:59
User entered 'spinal stenosis'	(b) (4), (b) (6)	25 Aug 2020 15:29:08

US3272315
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:28:14
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2017'	(b) (4), (b) (6)	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:29:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 2017'	System	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2017'	System	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:08

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:30:00
User entered 'hyperlipidemia'	(b) (4), (b) (6)	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2000'	(b) (4), (b) (6)	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:36

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 2000'	System	25 Aug 2020 15:29:36

US3272315
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:28:14
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2000'	System	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:36

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:30:00
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:50

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:29:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:29:50

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1990'	System	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1990'	System	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:29:50

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:06:51
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:38:03
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:34:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:31:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:31:32
Data point term sent to Coder	System	25 Aug 2020 15:31:02
User entered 'hysterectomy'	(b) (4), (b) (6)	25 Aug 2020 15:30:12

Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:28:14
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:31:34
User entered 'Yes (Y)'		25 Aug 2020 15:30:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:31:34
User entered empty.		25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1990'	System	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1990'	System	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1990'	System	25 Aug 2020 15:31:34
User entered empty.	System	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1990'	System	25 Aug 2020 15:31:34
User entered empty.	System	25 Aug 2020 15:30:12

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:06:56
User closed query ' Per DM CLR: Please specify the laterality of OOPHORECOMY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).		11 Nov 2020 12:05:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy bilateral, LLT: Bilateral oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 06:03:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 06:03:39
Query ' Per DM CLR: Please specify the laterality of OOPHORECOMY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:37:53
Data point term sent to Coder	System	18 Sep 2020 19:37:51
Coding entries removed.	Ashley Bell (b) (4)	18 Sep 2020 19:37:47
User entered 'bilateral OOPHORECOMY' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:37:47
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:37:37

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
User opened query ' Per DM CLR: Please specify the laterality of OOPHORECOMY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:48:56
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		15 Sep 2020 07:48:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:33:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:33:30
Data point term sent to Coder	System	25 Aug 2020 15:31:02
User entered 'oophorecomy'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2004'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2004'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 2004'	System	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2004'	System	25 Aug 2020 15:30:33

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 2004'	System	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '2004'	System	25 Aug 2020 15:30:33

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:31:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:31:33
Data point term sent to Coder	System	25 Aug 2020 15:31:02
User entered 'codeine allergy'	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1975'	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1975'	System	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1975'	System	25 Aug 2020 15:30:49

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:30:49

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	25 Aug 2020 15:30:49

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:32:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:32:35
Data point term sent to Coder	System	25 Aug 2020 15:32:03
User entered 'menopause'	(b) (4), (b) (6)	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1985'	(b) (4), (b) (6)	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 17:55:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:55:14
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 17:55:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:55:08
User entered 'No (N)'		25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'UN UNK 1986' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:55:08
User entered empty.		25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 17:55:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:55:22
User opened query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	System	17 Nov 2020 17:55:14
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1985'	System	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1985'	System	25 Aug 2020 15:31:13

US3272315

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1986'	System	17 Nov 2020 17:55:08
User entered empty.	System	25 Aug 2020 15:31:13

US3272315
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1986'	System	17 Nov 2020 17:55:08
User entered empty.	System	25 Aug 2020 15:31:13

US3272315
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:28:14
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
Data point term sent to Coder	System	18 Sep 2020 19:37:49
User entered 'Menorrhagia'	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Sep 2020 22:40:59
User entered 'UN UNK 1989' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 22:40:59
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Sep 2020 19:37:05
User entered empty.	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:37:12
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:37:05
User entered empty.	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990'	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Ashley Bell (b) (4)	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1989'	System	18 Sep 2020 22:40:59
User entered empty.	System	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1989'	System	18 Sep 2020 22:40:59
User entered empty.	System	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1990'	System	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:14

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1990'	System	18 Sep 2020 19:37:05

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:11:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:11:48
Data point term sent to Coder	System	17 Nov 2020 17:56:02
User entered 'post-menopausal'	(b) (4), (b) (6)	17 Nov 2020 17:56:01

US3272315
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:28:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'UN UNK 1986'	(b) (4), (b) (6)	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:56:01

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:56:01

US3272315
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:28:14
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'Jan 1986'	System	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '1986'	System	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:14

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	17 Nov 2020 17:56:01

US3272315
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:28:14
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered empty.	System	17 Nov 2020 17:56:01

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:46:15
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'UPDATED' (Site from DM).		25 Sep 2020 22:48:55
User entered 'Yes (Y)' reason for change: Data Entry Error		25 Sep 2020 22:48:29
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).		25 Sep 2020 14:23:01
User entered 'No (N)' reason for change: Data Entry Error		16 Sep 2020 21:43:45
User entered 'Yes (Y)'		25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error		16 Sep 2020 21:43:45
User entered '23 Aug 2020'		25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '11:00' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error		16 Sep 2020 21:43:45
User entered '11:00'		25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '23 Aug 2020 11:00'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered '23 Aug 2020 11:00'	System	25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '160.0' cm reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error		16 Sep 2020 21:43:45
User entered '160' cm		25 Aug 2020 15:28:09
DataPoint set to visible.	System	23 Aug 2020 17:31:41

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '90.5' kg reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error		16 Sep 2020 21:43:45
User entered '90.5' kg		25 Aug 2020 15:28:09
DataPoint set to visible.	System	23 Aug 2020 17:31:41

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered '35.35156'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered '35.4'	System	25 Aug 2020 15:28:09
DataPoint set to visible.	System	23 Aug 2020 17:31:41

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'kg/m2'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered 'kg/m2'	System	25 Aug 2020 15:28:09
DataPoint set to visible.	System	23 Aug 2020 17:31:41

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:46:18
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 22:48:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:23:06
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).		25 Sep 2020 14:23:06
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).		16 Sep 2020 21:43:50
User entered empty; reason for change Data Entry Error		16 Sep 2020 21:43:45
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).		16 Sep 2020 08:41:23

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:45
User entered 'Oral (Oral)'		25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:45
User entered '84'		25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'bpm'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered 'bpm'	System	25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:45
User entered '13'		25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'breaths/min'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered 'breaths/min'	System	25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:45
User entered '137'		25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'mmHg'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered 'mmHg'	System	25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 22:48:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:43:45
User entered '74'		25 Aug 2020 15:28:09

US3272315

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User entered 'mmHg'	System	25 Sep 2020 22:48:29
User entered empty.	System	16 Sep 2020 21:43:45
User entered 'mmHg'	System	25 Aug 2020 15:28:09

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45

US3272315
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45

US3272315

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:27:33

Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:27:33

US3272315
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:28:14
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:28:14
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'UN UNK 1986' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:56:13
User entered 'un UNK 1985'		25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:14

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:26

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:28:14
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:14

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:46:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:27:07

US3272315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:31:57

FDA-CBER-2022-1614-1648674

US3272315

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:31:57

US3272315
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 15:31:57

US3272315
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'VISIT1'	System	25 Aug 2020 15:31:57

FDA-CBER-2022-1614-1648677

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:15

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '187851'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:15

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Aug 2020 16:44:15

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:26:41

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:26:41

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:26:41

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:26:41

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:26:41

US3272315

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:14

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:54:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:22:57

US3272315
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:48:33
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:27:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:08:04
User entered '160' cm	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User entered '90.5' kg	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:48:33
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:27:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:08:04
User entered '160' cm	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User entered '90.5' kg	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User accepted default value 'Pre-Dose (PREDOSE)'		25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:00'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '23 Aug 2020 11:00'	System	25 Aug 2020 15:33:11

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.6' C	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '84'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'bpm'	System	25 Aug 2020 15:33:11

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'breaths/min'	System	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '137'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'mmHg'	System	25 Aug 2020 15:33:11

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '74'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'mmHg'	System	25 Aug 2020 15:33:11

US3272315
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:48:33
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:27:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:08:04
User entered '160' cm	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:27:15
User entered '90.5' kg	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User accepted default value 'Post-Dose (POSTDOSE)'		25 Aug 2020 15:33:11

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12:54'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '23 Aug 2020 12:54'	System	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.7' C	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '93'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'bpm'	System	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '16'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'breaths/min'	System	25 Aug 2020 15:33:11

FDA-CBER-2022-1614-1648720

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '132'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'mmHg'	System	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '82'	(b) (4), (b) (6)	25 Aug 2020 15:33:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'mmHg'	System	25 Aug 2020 15:33:11

US3272315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:33:43

US3272315

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:33:43

US3272315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

US3272315
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:28:14
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

US3272315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

US3272315
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:28:14
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'MRNA-1273 OR PLACEBO'	System	23 Aug 2020 17:32:01

US3272315
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

US3272315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12:12'	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

US3272315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '23 Aug 2020 12:12'	System	23 Aug 2020 17:32:01

US3272315

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	23 Aug 2020 17:32:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'ONCE'	System	23 Aug 2020 17:32:01

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US3272315
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:28:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered 'INTRAMUSCULAR'	System	23 Aug 2020 17:32:01

US3272315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:34:05

US3272315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:34:05

US3272315

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:30'	(b) (4), (b) (6)	25 Aug 2020 15:34:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '23 Aug 2020 11:30'	System	25 Aug 2020 15:34:05

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:14

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:27'	(b) (4), (b) (6)	25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '23 Aug 2020 11:27'	System	25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:34:17

US3272315

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:34:17

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered empty.	System	25 Aug 2020 15:34:17

US3272315
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:34:22

US3272315

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:22:48
User entered '1'	System	25 Aug 2020 15:34:22

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:55:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered 'Yes (Y)'	System	23 Aug 2020 17:56:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:55:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered '98.0'	System	23 Aug 2020 17:56:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:56:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered 'Yes (Y)'	System	23 Aug 2020 17:56:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:15:45
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:03:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Aug 2020 17:56:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:56:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered '1'	System	23 Aug 2020 17:56:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:56:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered '0'	System	23 Aug 2020 17:56:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:56:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db68aeee-77d0-49e2-9396-9ae5f9b5f24c'	System	23 Aug 2020 17:56:29
User entered '23 Aug 2020 12:56'	System	23 Aug 2020 17:56:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 12:32'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:02'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:39:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered 'Yes (Y)'	System	23 Aug 2020 21:39:58

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:38:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered '98.8'	System	23 Aug 2020 21:39:58

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:38:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered 'Yes (Y)'	System	23 Aug 2020 21:39:58

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:00
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Aug 2020 21:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:39:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered '1'	System	23 Aug 2020 21:39:58

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:39:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered '0'	System	23 Aug 2020 21:39:58

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:39:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34392da7-1353-43d0-99b8-6e18fa92814a'	System	23 Aug 2020 21:39:58
User entered '23 Aug 2020 16:39'	System	23 Aug 2020 21:39:58

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:57'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 2'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:19:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered 'Yes (Y)'	System	24 Aug 2020 17:20:15

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:19:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered '98.2'	System	24 Aug 2020 17:20:15

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:19:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered 'Yes (Y)'	System	24 Aug 2020 17:20:15

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered '0'	System	24 Aug 2020 17:20:15

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:10
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:12
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Aug 2020 17:20:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered '1'	System	24 Aug 2020 17:20:15

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f818e2a6-9aa2-4340-9cdd-9d7bf3912dd3'	System	24 Aug 2020 17:20:15
User entered '24 Aug 2020 12:20'	System	24 Aug 2020 17:20:15

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 3'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:31:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered 'Yes (Y)'	System	25 Aug 2020 19:32:40

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:31:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered '98.9'	System	25 Aug 2020 19:32:40

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered 'Yes (Y)'	System	25 Aug 2020 19:32:40

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitan medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:18
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Aug 2020 19:32:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:08', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered '1'	System	25 Aug 2020 19:32:40

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:08', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered '0'	System	25 Aug 2020 19:32:40

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3d671818-a0ff-42bc-8c0b-5af58c58e953'	System	25 Aug 2020 19:32:40
User entered '25 Aug 2020 14:32'	System	25 Aug 2020 19:32:40

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 4'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered 'Yes (Y)'	System	26 Aug 2020 20:04:46

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered '98.1'	System	26 Aug 2020 20:04:46

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered 'Yes (Y)'	System	26 Aug 2020 20:04:46

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:27
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Aug 2020 20:04:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered '1'	System	26 Aug 2020 20:04:46

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US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered '0'	System	26 Aug 2020 20:04:46

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '476eba66-5144-4bce-8834-d065432f63e6'	System	26 Aug 2020 20:04:46
User entered '26 Aug 2020 15:04'	System	26 Aug 2020 20:04:46

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 5'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:34', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered 'Yes (Y)'	System	27 Aug 2020 17:33:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered '98.6'	System	27 Aug 2020 17:33:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered 'Yes (Y)'	System	27 Aug 2020 17:33:03

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:31
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Aug 2020 17:33:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered '1'	System	27 Aug 2020 17:33:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered '0'	System	27 Aug 2020 17:33:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:32:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fa5f5259-739f-44ef-8ff6-d8e36bc4d5fa'	System	27 Aug 2020 17:33:03
User entered '27 Aug 2020 12:32'	System	27 Aug 2020 17:33:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 6'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:32:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered 'Yes (Y)'	System	28 Aug 2020 20:33:05

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:32:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered '98.1'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:32:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered 'Yes (Y)'	System	28 Aug 2020 20:33:05

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:37
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:06:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Aug 2020 20:33:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:32:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered '1'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:32:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered '0'	System	28 Aug 2020 20:33:05

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8c2b497f-9484-49c5-93e3-4eadf7d41115'	System	28 Aug 2020 20:33:05
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 7'	System	23 Aug 2020 17:32:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1648816

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1648818

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	28 Aug 2020 20:33:05
User entered 'Day 8'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered 'Yes (Y)'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered '98.1'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered 'Yes (Y)'	System	30 Aug 2020 19:01:44

FDA-CBER-2022-1614-1648827

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:47
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:07:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Aug 2020 19:01:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered '1'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered '0'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:41', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '321df408-e7be-4c17-9db3-a0eff1f78568'	System	30 Aug 2020 19:01:44
User entered '30 Aug 2020 14:01'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:33:05

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	30 Aug 2020 19:01:44
User entered 'Day 9'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:57:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered 'Yes (Y)'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered '98.4'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered 'Yes (Y)'	System	31 Aug 2020 20:58:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:52
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:07:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	31 Aug 2020 20:58:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered '1'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered '0'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '91d6aedb-8d55-47a8-977f-4a32ecd03168'	System	31 Aug 2020 20:58:29
User entered '31 Aug 2020 15:58'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 19:01:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 19:01:44

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	30 Aug 2020 19:01:44
User entered 'Day 10'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered 'Yes (Y)'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:41', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered '99.1'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered 'Yes (Y)'	System	01 Sep 2020 20:09:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:16:57
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:07:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Sep 2020 20:09:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered '1'	System	01 Sep 2020 20:09:59

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US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered '0'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:09:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b1758ea-a2d0-4fbf-b96c-ff68887ce80e'	System	01 Sep 2020 20:09:59
User entered '01 Sep 2020 15:09'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 19:01:44

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	31 Aug 2020 20:58:29
User entered 'Day 11'	System	31 Aug 2020 20:58:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered 'Yes (Y)'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered '98.5'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered 'Yes (Y)'	System	02 Sep 2020 18:51:55

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:02
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:07:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Sep 2020 18:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered '1'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered '0'	System	02 Sep 2020 18:51:55

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:51:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd7f0e41-edba-4090-8933-86a144e1ba7d'	System	02 Sep 2020 18:51:55
User entered '02 Sep 2020 13:51'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:58:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:58:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	01 Sep 2020 20:09:59
User entered 'Day 12'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered 'Yes (Y)'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered '98.4'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered 'Yes (Y)'	System	03 Sep 2020 19:03:41

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:07
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 22:07:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Sep 2020 19:03:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered '1'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered '0'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bee03ca4-2532-4398-b6bb-8e2fc5d3c720'	System	03 Sep 2020 19:03:41
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:09:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:09:59

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	02 Sep 2020 18:51:55
User entered 'Day 13'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered 'Yes (Y)'	System	05 Sep 2020 05:29:51

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered '98.5'	System	05 Sep 2020 05:29:51

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered 'Yes (Y)'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:13
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 22:07:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Sep 2020 05:29:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered '1'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered '0'	System	05 Sep 2020 05:29:51

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:29:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9e0ae3c9-d9fb-4979-9d70-a85cca9094da'	System	05 Sep 2020 05:29:51
User entered '05 Sep 2020 00:29'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:51:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	03 Sep 2020 19:03:41
User entered 'Day 14'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered 'Yes (Y)'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered '98.4'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered 'Yes (Y)'	System	06 Sep 2020 05:01:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:18
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 22:08:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 05:01:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered '1'	System	06 Sep 2020 05:01:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered '0'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dd4a271c-9c26-4505-a3e4-a2edb01f2bb8'	System	06 Sep 2020 05:01:35
User entered '06 Sep 2020 00:01'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:41

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	05 Sep 2020 05:29:51
User entered 'Day 15'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered 'Yes (Y)'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered '98.8'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered 'Yes (Y)'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:25
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:08:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 21:05:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered '1'	System	06 Sep 2020 21:05:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered '0'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ee675e48-730d-4c4b-8932-4ff5f327b231'	System	06 Sep 2020 21:05:35
User entered '06 Sep 2020 16:05'	System	06 Sep 2020 21:05:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 05:29:51

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	06 Sep 2020 05:01:35
User entered 'Day 16'	System	06 Sep 2020 05:01:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:19:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered 'Yes (Y)'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:19:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered '98.7'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:19:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered 'Yes (Y)'	System	08 Sep 2020 06:20:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:30
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 22:08:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 06:20:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:19:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered '1'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:19:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered '0'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:20:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ca3575bd-2f66-4e41-925d-0ebb52cb9190'	System	08 Sep 2020 06:20:06
User entered '08 Sep 2020 01:20'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 05:01:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 05:01:35

FDA-CBER-2022-1614-1648904

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	06 Sep 2020 21:05:35
User entered 'Day 17'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered 'Yes (Y)'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered '98.3'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered 'Yes (Y)'	System	08 Sep 2020 23:25:03

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:35
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		09 Sep 2020 22:08:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 23:25:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered '1'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered '0'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:24:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4619feca-90b4-425c-91db-4fd85f64699d'	System	08 Sep 2020 23:25:03
User entered '08 Sep 2020 18:24'	System	08 Sep 2020 23:25:03

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 21:05:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	08 Sep 2020 06:20:06
User entered 'Day 18'	System	08 Sep 2020 06:20:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:09:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered 'Yes (Y)'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:09:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered '98.2'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:09:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered 'Yes (Y)'	System	10 Sep 2020 05:10:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:45
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication' (Site from System).		10 Sep 2020 14:39:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Sep 2020 05:10:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:09:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered '1'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:09:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered '0'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:10:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0adf6e56-1124-4c3a-8ca1-b72b05727c88'	System	10 Sep 2020 05:10:02
User entered '10 Sep 2020 00:10'	System	10 Sep 2020 05:10:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 06:20:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 06:20:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	08 Sep 2020 23:25:03
User entered 'Day 19'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:28', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered 'Yes (Y)'	System	11 Sep 2020 05:04:48

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered '97.8'	System	11 Sep 2020 05:04:48

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered 'Yes (Y)'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		16 Sep 2020 14:17:50
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication ' (Site from System).		11 Sep 2020 13:21:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Sep 2020 05:04:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered '1'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered '0'	System	11 Sep 2020 05:04:48

FDA-CBER-2022-1614-1648928

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a546a8ad-6608-402a-9c09-b8d5c2cc6849'	System	11 Sep 2020 05:04:48
User entered '11 Sep 2020 00:04'	System	11 Sep 2020 05:04:48

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 23:25:03

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 23:25:03

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	10 Sep 2020 05:10:02
User entered 'Day 20'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered 'Yes (Y)'	System	11 Sep 2020 22:48:34

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered '98.4'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered 'Yes (Y)'	System	11 Sep 2020 22:48:34

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 19:14:59
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 23:50:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Sep 2020 22:48:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered '1'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered '0'	System	11 Sep 2020 22:48:34

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '39050088-2506-43cb-9e93-df829476adb5'	System	11 Sep 2020 22:48:34
User entered '11 Sep 2020 17:48'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 05:10:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 05:10:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	11 Sep 2020 05:04:48
User entered 'Day 21'	System	11 Sep 2020 05:04:48

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:28:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered 'Yes (Y)'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered '99.1'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered 'Yes (Y)'	System	13 Sep 2020 01:29:16

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 19:15:09
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).		16 Sep 2020 23:50:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 01:29:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered '1'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered '0'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a6f183c8-b144-406a-840a-e7984b774ae1'	System	13 Sep 2020 01:29:16
User entered '12 Sep 2020 20:29'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 05:04:48

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	11 Sep 2020 22:48:34
User entered 'Day 22'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered 'Yes (Y)'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:16', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered '99.2'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered 'Yes (Y)'	System	14 Sep 2020 00:17:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 19:15:23
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).		16 Sep 2020 23:51:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 00:17:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered '1'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered '0'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '48d6a562-8d91-4b74-ad58-3ceb9a54089b'	System	14 Sep 2020 00:17:29
User entered '13 Sep 2020 19:17'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:48:34

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	13 Sep 2020 01:29:16
User entered 'Day 23'	System	13 Sep 2020 01:29:16

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:20:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered 'Yes (Y)'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered '98.9'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered 'Yes (Y)'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		29 Oct 2020 20:51:53
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).		16 Sep 2020 23:52:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 02:21:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered '1'	System	15 Sep 2020 02:21:36

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered '0'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '921a19b6-a5dc-4ab4-8671-177057b09baf'	System	15 Sep 2020 02:21:36
User entered '14 Sep 2020 21:21'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 01:29:16

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 01:29:16

FDA-CBER-2022-1614-1648967

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	14 Sep 2020 00:17:29
User entered 'Day 24'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered 'Yes (Y)'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered '99.2'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:41', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered 'Yes (Y)'	System	15 Sep 2020 18:58:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 13:22:23
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).		16 Sep 2020 23:53:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 18:58:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered '1'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered '0'	System	15 Sep 2020 18:58:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:58:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2bf9ad16-c3c4-4230-a691-f2685616bb1f'	System	15 Sep 2020 18:58:53
User entered '15 Sep 2020 13:58'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 00:17:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 00:17:29

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	15 Sep 2020 02:21:36
User entered 'Day 25'	System	15 Sep 2020 02:21:36

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:42:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered 'Yes (Y)'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:42:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered '98.1'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:42:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered 'Yes (Y)'	System	16 Sep 2020 20:43:08

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 19:14:35
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'no new medication taken' (Site from System).		16 Sep 2020 23:54:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 20:43:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:43:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered '1'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:43:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered '0'	System	16 Sep 2020 20:43:08

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:43:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f3f8aa5c-dbc1-4865-b384-34892b93e808'	System	16 Sep 2020 20:43:08
User entered '16 Sep 2020 15:43'	System	16 Sep 2020 20:43:08

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:21:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	15 Sep 2020 18:58:53
User entered 'Day 26'	System	15 Sep 2020 18:58:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered 'Yes (Y)'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered '99.1'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered 'Yes (Y)'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		01 Nov 2020 10:12:03
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt took normal meds. pt re-educated. ' (Site from System).	Ashley Bell (b) (4)	18 Sep 2020 19:35:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Sep 2020 18:31:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered '1'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered '0'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f9711cf6-768f-433a-ba5f-f008d2c89a7a'	System	17 Sep 2020 18:31:22
User entered '17 Sep 2020 13:31'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 18:58:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	16 Sep 2020 20:43:08
User entered 'Day 27'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered 'Yes (Y)'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered '98.2'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:51', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered 'Yes (Y)'	System	18 Sep 2020 23:00:04

FDA-CBER-2022-1614-1648998

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitan medication pages. Thank you.' (Site from System).		12 Nov 2020 14:41:04
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED; ACETEMINOPHEN 1000MG TAKEN FOR GENERALIZED PAIN' (Site from System).		21 Sep 2020 23:19:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Sep 2020 23:00:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered '1'	System	18 Sep 2020 23:00:04

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered '0'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T17:59:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd843c734-0b2e-4d82-9f21-38297fc32cf1'	System	18 Sep 2020 23:00:04
User entered '18 Sep 2020 17:59'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:43:08

Folder: Diary Dose 1 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	17 Sep 2020 18:31:22
User entered 'Day 28'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered 'Yes (Y)'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered '98.9'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered 'Yes (Y)'	System	20 Sep 2020 05:00:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:41:24
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED; ACETEMINOPHEN 1000MG TAKEN FOR GENERALIZED PAIN' (Site from System).		21 Sep 2020 23:19:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	20 Sep 2020 05:00:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered '1'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered '0'	System	20 Sep 2020 05:00:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd04ccae5-0808-4e9f-8acc-2114f252adeb'	System	20 Sep 2020 05:00:53
User entered '20 Sep 2020 00:00'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(28)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	18 Sep 2020 23:00:04
User entered 'Day 29'	System	18 Sep 2020 23:00:04

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:18:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered 'Yes (Y)'	System	21 Sep 2020 05:19:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:18:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered '98.2'	System	21 Sep 2020 05:19:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:18:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered 'Yes (Y)'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:41:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED; ACETEMINOPHEN 1000MG TAKEN FOR GENERALIZED PAIN' (Site from System).		21 Sep 2020 23:19:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Sep 2020 05:19:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:19:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered '1'	System	21 Sep 2020 05:19:06

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US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:19:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered '0'	System	21 Sep 2020 05:19:06

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(29)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:19:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1f888952-422c-4281-8a4f-b4cb3b0c669c'	System	21 Sep 2020 05:19:06
User entered '21 Sep 2020 00:19'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	20 Sep 2020 05:00:53
User entered 'Day 30'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered 'Yes (Y)'	System	22 Sep 2020 05:36:28

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered '98.3'	System	22 Sep 2020 05:36:28

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered 'Yes (Y)'	System	22 Sep 2020 05:36:28

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitan medication pages. Thank you.' (Site from System).		12 Nov 2020 14:42:22
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient inadvertently pushed wrong button and only took normal medications listed in con meds' (Site from System).		24 Sep 2020 20:50:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 05:36:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered '1'	System	22 Sep 2020 05:36:28

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered '0'	System	22 Sep 2020 05:36:28

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(30)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0087d130-3b3b-4fcf-acfc-04e47cd9abed'	System	22 Sep 2020 05:36:28
User entered '22 Sep 2020 00:36'	System	22 Sep 2020 05:36:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 05:00:53

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US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 05:00:53

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	21 Sep 2020 05:19:06
User entered 'Day 31'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

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US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(31)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(32)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	22 Sep 2020 05:36:28
User entered 'Day 32'	System	22 Sep 2020 05:36:28

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered 'Yes (Y)'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered '98.5'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered 'Yes (Y)'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:42:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient inadvertently pushed wrong button and only took normal medications listed in con meds' (Site from System).		24 Sep 2020 20:50:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Sep 2020 19:55:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered '1'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered '0'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(32)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '89e9d088-4623-4ded-884b-3a39786d9376'	System	23 Sep 2020 19:55:47
User entered '23 Sep 2020 14:55'	System	23 Sep 2020 19:55:47

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(32)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 05:36:28

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(32)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 05:36:28

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Sep 2020 19:55:47
User entered 'Day 33'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:08', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered 'Yes (Y)'	System	25 Sep 2020 04:02:30

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered '98.0'	System	25 Sep 2020 04:02:30

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered 'Yes (Y)'	System	25 Sep 2020 04:02:30

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:42:54
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports to staff she is just taking her normal medications.' (Site from System).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 16:44:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 04:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered '1'	System	25 Sep 2020 04:02:30

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:43:09
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 16:44:26
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 04:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered '1'	System	25 Sep 2020 04:02:30

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(33)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4672eb59-b5ed-48e3-bd61-d574a410903f'	System	25 Sep 2020 04:02:30
User entered '24 Sep 2020 23:02'	System	25 Sep 2020 04:02:30

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:55:47

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(33)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:55:47

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Sep 2020 19:55:47
User entered 'Day 34'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:16', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered 'Yes (Y)'	System	25 Sep 2020 23:17:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered '99.2'	System	25 Sep 2020 23:17:35

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered 'Yes (Y)'	System	25 Sep 2020 23:17:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 14:43:21
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 16:44:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 23:17:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered '1'	System	25 Sep 2020 23:17:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered '0'	System	25 Sep 2020 23:17:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '4155ef6d-7ca9-477a-b785-27019a6bfc71'	System	25 Sep 2020 23:17:35
User entered '25 Sep 2020 18:17'	System	25 Sep 2020 23:17:35

US3272315
Folder: Diary Dose 1 (1)
Form: Temperature_Day(34)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Temperature_Day(34)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:55:47

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:51:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9ed9f359-5d3b-4dcc-ad0c-7e8a72451f58'	System	23 Aug 2020 17:52:24
User entered 'None (1)'	System	23 Aug 2020 17:52:24

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:51:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9ed9f359-5d3b-4dcc-ad0c-7e8a72451f58'	System	23 Aug 2020 17:52:24
User entered 'No (N)'	System	23 Aug 2020 17:52:24

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:51:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9ed9f359-5d3b-4dcc-ad0c-7e8a72451f58'	System	23 Aug 2020 17:52:24
User entered 'No (N)'	System	23 Aug 2020 17:52:24

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:51:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9ed9f359-5d3b-4dcc-ad0c-7e8a72451f58'	System	23 Aug 2020 17:52:24
User entered 'None (1)'	System	23 Aug 2020 17:52:24

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:52:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9ed9f359-5d3b-4dcc-ad0c-7e8a72451f58'	System	23 Aug 2020 17:52:24
User entered '23 Aug 2020 12:52'	System	23 Aug 2020 17:52:24

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 12:32'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:02'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:40:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0dd05a0e-85ac-4655-8946-7130993c21a5'	System	23 Aug 2020 21:40:56
User entered 'None (1)'	System	23 Aug 2020 21:40:56

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:40:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0dd05a0e-85ac-4655-8946-7130993c21a5'	System	23 Aug 2020 21:40:56
User entered 'No (N)'	System	23 Aug 2020 21:40:56

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:40:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0dd05a0e-85ac-4655-8946-7130993c21a5'	System	23 Aug 2020 21:40:56
User entered 'No (N)'	System	23 Aug 2020 21:40:56

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:40:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0dd05a0e-85ac-4655-8946-7130993c21a5'	System	23 Aug 2020 21:40:56
User entered 'None (1)'	System	23 Aug 2020 21:40:56

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:40:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0dd05a0e-85ac-4655-8946-7130993c21a5'	System	23 Aug 2020 21:40:56
User entered '23 Aug 2020 16:40'	System	23 Aug 2020 21:40:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:57'	System	23 Aug 2020 17:32:01

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US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 2'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:15:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered 'None (1)'	System	24 Aug 2020 17:18:23

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:15:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered 'Yes (Y)'	System	24 Aug 2020 17:18:23

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:18:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered '3'	System	24 Aug 2020 17:18:23

FDA-CBER-2022-1614-1649086

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:18:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered 'No (N)'	System	24 Aug 2020 17:18:23

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:18:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered 'None (1)'	System	24 Aug 2020 17:18:23

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:18:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b29708e7-d330-46e4-8fe6-6e34ae644727'	System	24 Aug 2020 17:18:23
User entered '24 Aug 2020 12:18'	System	24 Aug 2020 17:18:23

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 3'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccd83d10-40f0-4a50-8a50-ebb2fdc5f608'	System	25 Aug 2020 19:33:17
User entered 'None (1)'	System	25 Aug 2020 19:33:17

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccd83d10-40f0-4a50-8a50-ebb2fdc5f608'	System	25 Aug 2020 19:33:17
User entered 'No (N)'	System	25 Aug 2020 19:33:17

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccd83d10-40f0-4a50-8a50-ebb2fdc5f608'	System	25 Aug 2020 19:33:17
User entered 'No (N)'	System	25 Aug 2020 19:33:17

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:32:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccd83d10-40f0-4a50-8a50-ebb2fdc5f608'	System	25 Aug 2020 19:33:17
User entered 'None (1)'	System	25 Aug 2020 19:33:17

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccd83d10-40f0-4a50-8a50-ebb2fdc5f608'	System	25 Aug 2020 19:33:17
User entered '25 Aug 2020 14:33'	System	25 Aug 2020 19:33:17

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 4'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '33523353-de12-4506-aecc-051f5703d180'	System	26 Aug 2020 20:05:10
User entered 'None (1)'	System	26 Aug 2020 20:05:10

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '33523353-de12-4506-aecc-051f5703d180'	System	26 Aug 2020 20:05:10
User entered 'No (N)'	System	26 Aug 2020 20:05:10

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:04:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '33523353-de12-4506-aecc-051f5703d180'	System	26 Aug 2020 20:05:10
User entered 'No (N)'	System	26 Aug 2020 20:05:10

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '33523353-de12-4506-aecc-051f5703d180'	System	26 Aug 2020 20:05:10
User entered 'None (1)'	System	26 Aug 2020 20:05:10

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '33523353-de12-4506-aecc-051f5703d180'	System	26 Aug 2020 20:05:10
User entered '26 Aug 2020 15:05'	System	26 Aug 2020 20:05:10

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 5'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1311e884-de11-4f7d-a49e-5a211810b0b2'	System	27 Aug 2020 17:33:20
User entered 'None (1)'	System	27 Aug 2020 17:33:20

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1311e884-de11-4f7d-a49e-5a211810b0b2'	System	27 Aug 2020 17:33:20
User entered 'No (N)'	System	27 Aug 2020 17:33:20

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1311e884-de11-4f7d-a49e-5a211810b0b2'	System	27 Aug 2020 17:33:20
User entered 'No (N)'	System	27 Aug 2020 17:33:20

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1311e884-de11-4f7d-a49e-5a211810b0b2'	System	27 Aug 2020 17:33:20
User entered 'None (1)'	System	27 Aug 2020 17:33:20

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:19', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '1311e884-de11-4f7d-a49e-5a211810b0b2'	System	27 Aug 2020 17:33:20
User entered '27 Aug 2020 12:33'	System	27 Aug 2020 17:33:20

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

FDA-CBER-2022-1614-1649115

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 6'	System	23 Aug 2020 17:32:01

FDA-CBER-2022-1614-1649116

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b087f970-f927-499b-a23e-381d5bf2aec8'	System	28 Aug 2020 20:33:25
User entered 'None (1)'	System	28 Aug 2020 20:33:25

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b087f970-f927-499b-a23e-381d5bf2aec8'	System	28 Aug 2020 20:33:25
User entered 'No (N)'	System	28 Aug 2020 20:33:25

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:14', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b087f970-f927-499b-a23e-381d5bf2aec8'	System	28 Aug 2020 20:33:25
User entered 'No (N)'	System	28 Aug 2020 20:33:25

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b087f970-f927-499b-a23e-381d5bf2aec8'	System	28 Aug 2020 20:33:25
User entered 'None (1)'	System	28 Aug 2020 20:33:25

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b087f970-f927-499b-a23e-381d5bf2aec8'	System	28 Aug 2020 20:33:25
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:33:25

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 7'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649127

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649128

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)	26 Feb 2021 03:39:02

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649130

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:52:34', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:52:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:53:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:53:08', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:53:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:53:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'None (0)'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:54:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered 'No (N)'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T12:54:16', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7a8f088a-5ad9-4a6f-8f62-1063190b572d'	System	23 Aug 2020 17:54:22
User entered '23 Aug 2020 12:54'	System	23 Aug 2020 17:54:22

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 12:32'	System	23 Aug 2020 17:32:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:02'	System	23 Aug 2020 17:32:01

FDA-CBER-2022-1614-1649144

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 1, after vaccination (at home)'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:19', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'None (0)'	System	23 Aug 2020 21:41:41

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered 'No (N)'	System	23 Aug 2020 21:41:41

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-23T16:41:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59beae20-35b6-4c45-8ce8-6750b68f5e59'	System	23 Aug 2020 21:41:41
User entered '23 Aug 2020 16:41'	System	23 Aug 2020 21:41:41

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Aug 2020 15:57'	System	23 Aug 2020 17:32:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 2'	System	23 Aug 2020 17:32:01

FDA-CBER-2022-1614-1649156

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:21:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'None (0)'	System	24 Aug 2020 17:21:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:34', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'None (0)'	System	24 Aug 2020 17:21:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'None (0)'	System	24 Aug 2020 17:21:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:41', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'None (0)'	System	24 Aug 2020 17:21:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'None (0)'	System	24 Aug 2020 17:21:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered 'No (N)'	System	24 Aug 2020 17:21:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-24T12:20:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b61ca001-ec1b-4019-ba28-391520a7b787'	System	24 Aug 2020 17:21:01
User entered '24 Aug 2020 12:20'	System	24 Aug 2020 17:21:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 3'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'None (0)'	System	25 Aug 2020 19:33:48

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered 'No (N)'	System	25 Aug 2020 19:33:48

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-25T14:33:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '8d0b3520-061c-47c5-af13-1a7e3677a377'	System	25 Aug 2020 19:33:48
User entered '25 Aug 2020 14:33'	System	25 Aug 2020 19:33:48

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 4'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:27', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'None (0)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered 'No (N)'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-26T15:05:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ceef4b9-ba80-4b6a-9b13-aff18ac62875'	System	26 Aug 2020 20:05:54
User entered '26 Aug 2020 15:05'	System	26 Aug 2020 20:05:54

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 5'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:28', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:33:55

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'None (0)'	System	27 Aug 2020 17:33:55

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:34', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'None (0)'	System	27 Aug 2020 17:33:55

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'None (0)'	System	27 Aug 2020 17:33:55

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'None (0)'	System	27 Aug 2020 17:33:55

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'None (0)'	System	27 Aug 2020 17:33:55

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered 'No (N)'	System	27 Aug 2020 17:33:55

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-27T12:33:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5fc921fa-5cf8-4527-bc3e-a4bccafd7ea6'	System	27 Aug 2020 17:33:55
User entered '27 Aug 2020 12:33'	System	27 Aug 2020 17:33:55

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

FDA-CBER-2022-1614-1649198

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 6'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:27', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:45', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'None (0)'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered 'No (N)'	System	28 Aug 2020 20:33:58

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-28T15:33:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '758ebb74-ef18-45e3-81ca-c4c771c0a154'	System	28 Aug 2020 20:33:58
User entered '28 Aug 2020 15:33'	System	28 Aug 2020 20:33:58

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 7'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Aug 2020 12:00'	System	23 Aug 2020 17:32:01

US3272315

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Aug 2020 11:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	28 Aug 2020 20:33:05
User entered 'Day 8'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:48', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccbdeb8e-689e-411a-9673-1ead99b21acd'	System	30 Aug 2020 19:01:56
User entered 'No (N)'	System	30 Aug 2020 19:01:56

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-30T14:01:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ccbdeb8e-689e-411a-9673-1ead99b21acd'	System	30 Aug 2020 19:01:56
User entered '30 Aug 2020 14:01'	System	30 Aug 2020 19:01:56

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:33:05

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:33:05

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	30 Aug 2020 19:01:44
User entered 'Day 9'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '025839ca-c850-4a70-9cc9-8ac538e8cedb'	System	31 Aug 2020 20:58:41
User entered 'No (N)'	System	31 Aug 2020 20:58:41

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-08-31T15:58:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '025839ca-c850-4a70-9cc9-8ac538e8cedb'	System	31 Aug 2020 20:58:41
User entered '31 Aug 2020 15:58'	System	31 Aug 2020 20:58:41

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 19:01:44

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 19:01:44

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	30 Aug 2020 19:01:44
User entered 'Day 10'	System	30 Aug 2020 19:01:44

FDA-CBER-2022-1614-1649232

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:10:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ab5612c-4642-4ce5-9d66-160e21650bc1'	System	01 Sep 2020 20:10:12
User entered 'No (N)'	System	01 Sep 2020 20:10:12

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-01T15:10:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ab5612c-4642-4ce5-9d66-160e21650bc1'	System	01 Sep 2020 20:10:12
User entered '01 Sep 2020 15:10'	System	01 Sep 2020 20:10:12

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 19:01:44

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 19:01:44

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	31 Aug 2020 20:58:29
User entered 'Day 11'	System	31 Aug 2020 20:58:29

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:52:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fe7115f2-a262-4a52-aac1-a6c6aa40f356'	System	02 Sep 2020 18:52:13
User entered 'No (N)'	System	02 Sep 2020 18:52:13

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-02T13:52:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fe7115f2-a262-4a52-aac1-a6c6aa40f356'	System	02 Sep 2020 18:52:13
User entered '02 Sep 2020 13:52'	System	02 Sep 2020 18:52:13

Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:58:29

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:58:29

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US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	01 Sep 2020 20:09:59
User entered 'Day 12'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'faddf67a-2512-46b8-80c2-2bab75c1b0db'	System	03 Sep 2020 19:04:00
User entered 'No (N)'	System	03 Sep 2020 19:04:00

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-03T14:03:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'faddf67a-2512-46b8-80c2-2bab75c1b0db'	System	03 Sep 2020 19:04:00
User entered '03 Sep 2020 14:03'	System	03 Sep 2020 19:04:00

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:09:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:09:59

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	02 Sep 2020 18:51:55
User entered 'Day 13'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:30:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '627e752e-ba79-4e01-8c89-030eb1b081f5'	System	05 Sep 2020 05:30:08
User entered 'No (N)'	System	05 Sep 2020 05:30:08

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-05T00:30:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '627e752e-ba79-4e01-8c89-030eb1b081f5'	System	05 Sep 2020 05:30:08
User entered '05 Sep 2020 00:30'	System	05 Sep 2020 05:30:08

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:51:55

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:51:55

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	03 Sep 2020 19:03:41
User entered 'Day 14'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '730b4f10-ef2b-4975-a72c-77752a01469d'	System	06 Sep 2020 05:01:42
User entered 'No (N)'	System	06 Sep 2020 05:01:42

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T00:01:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '730b4f10-ef2b-4975-a72c-77752a01469d'	System	06 Sep 2020 05:01:42
User entered '06 Sep 2020 00:01'	System	06 Sep 2020 05:01:42

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:03:41

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:03:41

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	05 Sep 2020 05:29:51
User entered 'Day 15'	System	05 Sep 2020 05:29:51

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3a5bd6e3-ae7e-4b6b-8320-691662516b4c'	System	06 Sep 2020 21:05:40
User entered 'No (N)'	System	06 Sep 2020 21:05:40

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-06T16:05:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3a5bd6e3-ae7e-4b6b-8320-691662516b4c'	System	06 Sep 2020 21:05:40
User entered '06 Sep 2020 16:05'	System	06 Sep 2020 21:05:40

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 05:29:51

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Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 05:29:51

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	06 Sep 2020 05:01:35
User entered 'Day 16'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:20:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '6a4cb45b-6b29-4c67-a73b-e84b7f2648c1'	System	08 Sep 2020 06:20:26
User entered 'No (N)'	System	08 Sep 2020 06:20:26

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T01:20:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '6a4cb45b-6b29-4c67-a73b-e84b7f2648c1'	System	08 Sep 2020 06:20:26
User entered '08 Sep 2020 01:20'	System	08 Sep 2020 06:20:26

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 05:01:35

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 05:01:35

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	06 Sep 2020 21:05:35
User entered 'Day 17'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:25:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c91a186c-507d-4ca7-bb5e-cbbfc64d094a'	System	08 Sep 2020 23:25:08
User entered 'No (N)'	System	08 Sep 2020 23:25:08

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-08T18:25:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c91a186c-507d-4ca7-bb5e-cbbfc64d094a'	System	08 Sep 2020 23:25:08
User entered '08 Sep 2020 18:25'	System	08 Sep 2020 23:25:08

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 21:05:35

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 21:05:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	08 Sep 2020 06:20:06
User entered 'Day 18'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:10:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f567e27d-66f8-45ff-b44e-b4d640735d51'	System	10 Sep 2020 05:10:11
User entered 'No (N)'	System	10 Sep 2020 05:10:11

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-10T00:10:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f567e27d-66f8-45ff-b44e-b4d640735d51'	System	10 Sep 2020 05:10:11
User entered '10 Sep 2020 00:10'	System	10 Sep 2020 05:10:11

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 06:20:06

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 06:20:06

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	08 Sep 2020 23:25:03
User entered 'Day 19'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34d59eda-817d-4feb-875b-f22d9943e9d6'	System	11 Sep 2020 05:04:59
User entered 'No (N)'	System	11 Sep 2020 05:04:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T00:04:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '34d59eda-817d-4feb-875b-f22d9943e9d6'	System	11 Sep 2020 05:04:59
User entered '11 Sep 2020 00:04'	System	11 Sep 2020 05:04:59

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 23:25:03

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 23:25:03

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	10 Sep 2020 05:10:02
User entered 'Day 20'	System	10 Sep 2020 05:10:02

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7ad914c9-d03d-46c8-9fab-5b385ff79684'	System	11 Sep 2020 22:48:45
User entered 'No (N)'	System	11 Sep 2020 22:48:45

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-11T17:48:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7ad914c9-d03d-46c8-9fab-5b385ff79684'	System	11 Sep 2020 22:48:45
User entered '11 Sep 2020 17:48'	System	11 Sep 2020 22:48:45

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 05:10:02

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 05:10:02

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US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	11 Sep 2020 05:04:48
User entered 'Day 21'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e58a8957-2621-495e-b0fd-15b815339e35'	System	13 Sep 2020 01:29:31
User entered 'No (N)'	System	13 Sep 2020 01:29:31

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-12T20:29:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e58a8957-2621-495e-b0fd-15b815339e35'	System	13 Sep 2020 01:29:31
User entered '12 Sep 2020 20:29'	System	13 Sep 2020 01:29:31

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 05:04:48

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	11 Sep 2020 22:48:34
User entered 'Day 22'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '40575f42-2923-4e47-8570-e9ef3cb4dca6'	System	14 Sep 2020 00:17:40
User entered 'No (N)'	System	14 Sep 2020 00:17:40

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-13T19:17:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '40575f42-2923-4e47-8570-e9ef3cb4dca6'	System	14 Sep 2020 00:17:40
User entered '13 Sep 2020 19:17'	System	14 Sep 2020 00:17:40

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:48:34

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:48:34

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	13 Sep 2020 01:29:16
User entered 'Day 23'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3bbe283f-8526-4850-a975-6ff32feb36c1'	System	15 Sep 2020 02:21:44
User entered 'No (N)'	System	15 Sep 2020 02:21:44

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-14T21:21:41', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3bbe283f-8526-4850-a975-6ff32feb36c1'	System	15 Sep 2020 02:21:44
User entered '14 Sep 2020 21:21'	System	15 Sep 2020 02:21:44

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 01:29:16

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 01:29:16

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	14 Sep 2020 00:17:29
User entered 'Day 24'	System	14 Sep 2020 00:17:29

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:59:14', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '57f6c14a-1007-4062-9c42-0bdd780f2ca0'	System	15 Sep 2020 18:59:25
User entered 'No (N)'	System	15 Sep 2020 18:59:25

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-15T13:59:19', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '57f6c14a-1007-4062-9c42-0bdd780f2ca0'	System	15 Sep 2020 18:59:25
User entered '15 Sep 2020 13:59'	System	15 Sep 2020 18:59:25

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 00:17:29

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 00:17:29

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	15 Sep 2020 02:21:36
User entered 'Day 25'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:43:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '49f39ffc-22f0-4c8a-b66a-c7df3de6d862'	System	16 Sep 2020 20:43:17
User entered 'No (N)'	System	16 Sep 2020 20:43:17

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-16T15:43:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '49f39ffc-22f0-4c8a-b66a-c7df3de6d862'	System	16 Sep 2020 20:43:17
User entered '16 Sep 2020 15:43'	System	16 Sep 2020 20:43:17

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:21:36

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:21:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	15 Sep 2020 18:58:53
User entered 'Day 26'	System	15 Sep 2020 18:58:53

FDA-CBER-2022-1614-1649312

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '593db33a-b388-4d31-8b01-49384e92732c'	System	17 Sep 2020 18:31:32
User entered 'No (N)'	System	17 Sep 2020 18:31:32

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-17T13:31:27', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '593db33a-b388-4d31-8b01-49384e92732c'	System	17 Sep 2020 18:31:32
User entered '17 Sep 2020 13:31'	System	17 Sep 2020 18:31:32

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 18:58:53

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	16 Sep 2020 20:43:08
User entered 'Day 27'	System	16 Sep 2020 20:43:08

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T18:00:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ae7bfe2-d345-4262-b942-191e81b0e271'	System	18 Sep 2020 23:00:16
User entered 'No (N)'	System	18 Sep 2020 23:00:16

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-18T18:00:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '0ae7bfe2-d345-4262-b942-191e81b0e271'	System	18 Sep 2020 23:00:16
User entered '18 Sep 2020 18:00'	System	18 Sep 2020 23:00:16

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 20:43:08

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 20:43:08

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	17 Sep 2020 18:31:22
User entered 'Day 28'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:00:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bb186e5c-05e1-4dea-bafd-61ca981082bb'	System	20 Sep 2020 05:01:06
User entered 'No (N)'	System	20 Sep 2020 05:01:06

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-20T00:01:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bb186e5c-05e1-4dea-bafd-61ca981082bb'	System	20 Sep 2020 05:01:06
User entered '20 Sep 2020 00:01'	System	20 Sep 2020 05:01:06

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:31:22

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:31:22

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	18 Sep 2020 23:00:04
User entered 'Day 29'	System	18 Sep 2020 23:00:04

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:19:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5ecdd108-eaae-48cd-bf33-bbafd04676d3'	System	21 Sep 2020 05:19:19
User entered 'No (N)'	System	21 Sep 2020 05:19:19

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-21T00:19:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5ecdd108-eaae-48cd-bf33-bbafd04676d3'	System	21 Sep 2020 05:19:19
User entered '21 Sep 2020 00:19'	System	21 Sep 2020 05:19:19

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 23:00:04

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 23:00:04

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	20 Sep 2020 05:00:53
User entered 'Day 30'	System	20 Sep 2020 05:00:53

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7f32471c-98d8-461a-84c5-e43974fa2de9'	System	22 Sep 2020 05:36:37
User entered 'No (N)'	System	22 Sep 2020 05:36:37

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-22T00:36:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7f32471c-98d8-461a-84c5-e43974fa2de9'	System	22 Sep 2020 05:36:37
User entered '22 Sep 2020 00:36'	System	22 Sep 2020 05:36:37

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 05:00:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 05:00:53

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	21 Sep 2020 05:19:06
User entered 'Day 31'	System	21 Sep 2020 05:19:06

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 05:19:06

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 05:19:06

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(32)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	22 Sep 2020 05:36:28
User entered 'Day 32'	System	22 Sep 2020 05:36:28

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(32)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'cc80fe96-0224-40c6-84cb-1450e75ba967'	System	23 Sep 2020 19:55:54
User entered 'No (N)'	System	23 Sep 2020 19:55:54

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-23T14:55:51', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'cc80fe96-0224-40c6-84cb-1450e75ba967'	System	23 Sep 2020 19:55:54
User entered '23 Sep 2020 14:55'	System	23 Sep 2020 19:55:54

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 05:36:28

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(32)
Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 05:36:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Sep 2020 19:55:47
User entered 'Day 33'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '51058115-f022-4aaa-ad0d-feefd753c146'	System	25 Sep 2020 04:02:38
User entered 'No (N)'	System	25 Sep 2020 04:02:38

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-24T23:02:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '51058115-f022-4aaa-ad0d-feefd753c146'	System	25 Sep 2020 04:02:38
User entered '24 Sep 2020 23:02'	System	25 Sep 2020 04:02:38

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:55:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Sep 2020 19:55:47
User entered 'Day 34'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '85cfdd31-ab8c-4261-80ab-f8c5752e7d4a'	System	25 Sep 2020 23:17:42
User entered 'No (N)'	System	25 Sep 2020 23:17:42

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(34)
Generated On: 09 Jun 2021 16:28:14
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-25T18:17:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '85cfdd31-ab8c-4261-80ab-f8c5752e7d4a'	System	25 Sep 2020 23:17:42
User entered '25 Sep 2020 18:17'	System	25 Sep 2020 23:17:42

US3272315
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(34)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:55:47

US3272315

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:55:47

US3272315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:46:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:46:24

US3272315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 19:46:24

US3272315

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:46:24

US3272315

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:46:28

Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:23
User entered '1'	System	31 Aug 2020 19:46:28

US3272315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	Kayla Flege (b) (4)	08 Sep 2020 23:26:11
	(b) (4)	

US3272315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '8 Sep 2020'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 23:26:11

US3272315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 23:26:11

US3272315

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 23:26:11

US3272315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 23:26:15

US3272315

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:41
User entered '1'	System	08 Sep 2020 23:26:15

US3272315
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:37:48

US3272315
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:37:48

US3272315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 18:37:48

US3272315

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:37:48

US3272315
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:37:56

US3272315

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:29
User entered '1'	System	14 Sep 2020 18:37:56

US3272315
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:09:34

US3272315
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:09:34

US3272315

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 19:09:34

US3272315
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'VISIT2'	System	26 Sep 2020 19:09:34

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User accepted default value 'Pre-Dose (PREDOSE)'		26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '11:11'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered '26 Sep 2020 11:11'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '36.6' C	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '98'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'bpm'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '20'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'breaths/min'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '130'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'mmHg'	System	26 Sep 2020 19:11:22

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '78'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

FDA-CBER-2022-1614-1649393

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'mmHg'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User accepted default value 'Post-Dose (POSTDOSE)'		26 Sep 2020 19:11:22

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '12:35'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered '26 Sep 2020 12:35'	System	26 Sep 2020 19:11:22

US3272315
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '37.3' C	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

US3272315
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '91'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'bpm'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '20'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'breaths/min'	System	26 Sep 2020 19:11:22

FDA-CBER-2022-1614-1649406

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '112'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'mmHg'	System	26 Sep 2020 19:11:22

US3272315

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '80'	(b) (4), (b) (6)	26 Sep 2020 19:11:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:57
User entered 'mmHg'	System	26 Sep 2020 19:11:22

FDA-CBER-2022-1614-1649410

US3272315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:11:43

US3272315

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:11:43

US3272315
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

US3272315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

US3272315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

US3272315
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649416

US3272315

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '26 Sep 2020'	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12:04'	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

US3272315
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered '26 Sep 2020 12:04'	System	26 Sep 2020 17:09:35

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649420

US3272315
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered 'ONCE'	System	26 Sep 2020 17:09:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649422

US3272315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:12:03

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:12:03

FDA-CBER-2022-1614-1649424

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:30'	(b) (4), (b) (6)	26 Sep 2020 19:12:03

FDA-CBER-2022-1614-1649425

US3272315

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered '26 Sep 2020 11:30'	System	26 Sep 2020 19:12:03

US3272315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:12:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		26 Sep 2020 19:12:15

FDA-CBER-2022-1614-1649428

US3272315
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:12:15

US3272315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:22'	(b) (4), (b) (6)	26 Sep 2020 19:12:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered '26 Sep 2020 11:22'	System	26 Sep 2020 19:12:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		26 Sep 2020 19:12:15

FDA-CBER-2022-1614-1649432

US3272315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 19:12:15

US3272315

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:12:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered empty.	System	26 Sep 2020 19:12:15

FDA-CBER-2022-1614-1649435

US3272315

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:12:23

US3272315
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:38:43
User entered '1'	System	26 Sep 2020 19:12:23

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:34:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4cf8d09-50b3-442d-8a89-2451a8c72c5a'	System	26 Sep 2020 17:35:35
User entered 'Yes (Y)'	System	26 Sep 2020 17:35:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:34:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4cf8d09-50b3-442d-8a89-2451a8c72c5a'	System	26 Sep 2020 17:35:35
User entered '99.3'	System	26 Sep 2020 17:35:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:35:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4cf8d09-50b3-442d-8a89-2451a8c72c5a'	System	26 Sep 2020 17:35:35
User entered 'No (N)'	System	26 Sep 2020 17:35:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:35:29', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4cf8d09-50b3-442d-8a89-2451a8c72c5a'	System	26 Sep 2020 17:35:35
User entered '26 Sep 2020 12:35'	System	26 Sep 2020 17:35:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 12:24'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649443

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 14:54'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:12:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '305e8823-bcdc-4bad-8ca1-de8228b3ef65'	System	27 Sep 2020 15:13:14
User entered 'Yes (Y)'	System	27 Sep 2020 15:13:14

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:13:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '305e8823-bcdc-4bad-8ca1-de8228b3ef65'	System	27 Sep 2020 15:13:14
User entered '98.5'	System	27 Sep 2020 15:13:14

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:13:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '305e8823-bcdc-4bad-8ca1-de8228b3ef65'	System	27 Sep 2020 15:13:14
User entered 'No (N)'	System	27 Sep 2020 15:13:14

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:13:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '305e8823-bcdc-4bad-8ca1-de8228b3ef65'	System	27 Sep 2020 15:13:14
User entered '27 Sep 2020 10:13'	System	27 Sep 2020 15:13:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 15:49'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649450

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649451

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 2'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:56:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c210027e-8105-4c68-a6a1-026e1c0b6b10'	System	27 Sep 2020 23:57:08
User entered 'Yes (Y)'	System	27 Sep 2020 23:57:08

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:56:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c210027e-8105-4c68-a6a1-026e1c0b6b10'	System	27 Sep 2020 23:57:08
User entered '98.5'	System	27 Sep 2020 23:57:08

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c210027e-8105-4c68-a6a1-026e1c0b6b10'	System	27 Sep 2020 23:57:08
User entered 'No (N)'	System	27 Sep 2020 23:57:08

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:05', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c210027e-8105-4c68-a6a1-026e1c0b6b10'	System	27 Sep 2020 23:57:08
User entered '27 Sep 2020 18:57'	System	27 Sep 2020 23:57:08

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649458

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 3'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649461

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 4'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:07:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4636ca3-54fe-4d36-a273-9d15ff861c98'	System	30 Sep 2020 03:08:18
User entered 'Yes (Y)'	System	30 Sep 2020 03:08:18

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4636ca3-54fe-4d36-a273-9d15ff861c98'	System	30 Sep 2020 03:08:18
User entered '98.3'	System	30 Sep 2020 03:08:18

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:08', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4636ca3-54fe-4d36-a273-9d15ff861c98'	System	30 Sep 2020 03:08:18
User entered 'No (N)'	System	30 Sep 2020 03:08:18

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a4636ca3-54fe-4d36-a273-9d15ff861c98'	System	30 Sep 2020 03:08:18
User entered '29 Sep 2020 22:08'	System	30 Sep 2020 03:08:18

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 5'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:01:32', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2d6c784c-750b-4c53-bccc-3d17edd51d9c'	System	01 Oct 2020 02:01:51
User entered 'Yes (Y)'	System	01 Oct 2020 02:01:51

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:01:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2d6c784c-750b-4c53-bccc-3d17edd51d9c'	System	01 Oct 2020 02:01:51
User entered '99.1'	System	01 Oct 2020 02:01:51

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:01:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2d6c784c-750b-4c53-bccc-3d17edd51d9c'	System	01 Oct 2020 02:01:51
User entered 'No (N)'	System	01 Oct 2020 02:01:51

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:01:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2d6c784c-750b-4c53-bccc-3d17edd51d9c'	System	01 Oct 2020 02:01:51
User entered '30 Sep 2020 21:01'	System	01 Oct 2020 02:01:51

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 6'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:03:28', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b090c1f-e7bf-4b20-853c-3fb660979d18'	System	02 Oct 2020 07:03:54
User entered 'Yes (Y)'	System	02 Oct 2020 07:03:54

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:03:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b090c1f-e7bf-4b20-853c-3fb660979d18'	System	02 Oct 2020 07:03:54
User entered '98.2'	System	02 Oct 2020 07:03:54

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:03:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b090c1f-e7bf-4b20-853c-3fb660979d18'	System	02 Oct 2020 07:03:54
User entered 'No (N)'	System	02 Oct 2020 07:03:54

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:03:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '7b090c1f-e7bf-4b20-853c-3fb660979d18'	System	02 Oct 2020 07:03:54
User entered '02 Oct 2020 02:03'	System	02 Oct 2020 07:03:54

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

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US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 7'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649491

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649493

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:35:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '489bab9a-9c9f-4bdc-955b-b39ba119b583'	System	26 Sep 2020 17:37:50
User entered 'None (1)'	System	26 Sep 2020 17:37:50

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:36:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '489bab9a-9c9f-4bdc-955b-b39ba119b583'	System	26 Sep 2020 17:37:50
User entered 'No (N)'	System	26 Sep 2020 17:37:50

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:36:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '489bab9a-9c9f-4bdc-955b-b39ba119b583'	System	26 Sep 2020 17:37:50
User entered 'No (N)'	System	26 Sep 2020 17:37:50

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:36:13', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '489bab9a-9c9f-4bdc-955b-b39ba119b583'	System	26 Sep 2020 17:37:50
User entered 'None (1)'	System	26 Sep 2020 17:37:50

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:37:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '489bab9a-9c9f-4bdc-955b-b39ba119b583'	System	26 Sep 2020 17:37:50
User entered '26 Sep 2020 12:37'	System	26 Sep 2020 17:37:50

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 12:24'	System	26 Sep 2020 17:09:35

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US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 14:54'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:13:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered 'None (1)'	System	27 Sep 2020 15:15:16

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:13:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered 'Yes (Y)'	System	27 Sep 2020 15:15:16

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:14:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered '1'	System	27 Sep 2020 15:15:16

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered 'No (N)'	System	27 Sep 2020 15:15:16

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered 'None (1)'	System	27 Sep 2020 15:15:16

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e72189fb-d5dc-4ea6-a79e-edc95b280000'	System	27 Sep 2020 15:15:16
User entered '27 Sep 2020 10:15'	System	27 Sep 2020 15:15:16

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 15:49'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 2'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c2169b14-b712-4347-aecb-77e38432a157'	System	27 Sep 2020 23:57:37
User entered 'None (1)'	System	27 Sep 2020 23:57:37

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:14', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c2169b14-b712-4347-aecb-77e38432a157'	System	27 Sep 2020 23:57:37
User entered 'No (N)'	System	27 Sep 2020 23:57:37

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:21', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c2169b14-b712-4347-aecb-77e38432a157'	System	27 Sep 2020 23:57:37
User entered 'No (N)'	System	27 Sep 2020 23:57:37

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c2169b14-b712-4347-aecb-77e38432a157'	System	27 Sep 2020 23:57:37
User entered 'None (1)'	System	27 Sep 2020 23:57:37

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:28', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'c2169b14-b712-4347-aecb-77e38432a157'	System	27 Sep 2020 23:57:37
User entered '27 Sep 2020 18:57'	System	27 Sep 2020 23:57:37

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

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US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 3'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02

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US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649531

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 4'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a56671d1-2d64-4c55-950d-0866755d8ee7'	System	30 Sep 2020 03:08:40
User entered 'None (1)'	System	30 Sep 2020 03:08:40

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a56671d1-2d64-4c55-950d-0866755d8ee7'	System	30 Sep 2020 03:08:40
User entered 'No (N)'	System	30 Sep 2020 03:08:40

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a56671d1-2d64-4c55-950d-0866755d8ee7'	System	30 Sep 2020 03:08:40
User entered 'No (N)'	System	30 Sep 2020 03:08:40

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a56671d1-2d64-4c55-950d-0866755d8ee7'	System	30 Sep 2020 03:08:40
User entered 'None (1)'	System	30 Sep 2020 03:08:40

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:28:14
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a56671d1-2d64-4c55-950d-0866755d8ee7'	System	30 Sep 2020 03:08:40
User entered '29 Sep 2020 22:08'	System	30 Sep 2020 03:08:40

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

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US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 5'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dcc9d698-a834-4306-aac2-f2a4e326835e'	System	01 Oct 2020 02:02:39
User entered 'None (1)'	System	01 Oct 2020 02:02:39

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dcc9d698-a834-4306-aac2-f2a4e326835e'	System	01 Oct 2020 02:02:39
User entered 'No (N)'	System	01 Oct 2020 02:02:39

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:28:14
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dcc9d698-a834-4306-aac2-f2a4e326835e'	System	01 Oct 2020 02:02:39
User entered 'No (N)'	System	01 Oct 2020 02:02:39

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dcc9d698-a834-4306-aac2-f2a4e326835e'	System	01 Oct 2020 02:02:39
User entered 'None (1)'	System	01 Oct 2020 02:02:39

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'dcc9d698-a834-4306-aac2-f2a4e326835e'	System	01 Oct 2020 02:02:39
User entered '30 Sep 2020 21:02'	System	01 Oct 2020 02:02:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649547

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 6'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '610d5591-3ca1-44f2-8dfc-e2fc9ef30a7b'	System	02 Oct 2020 07:04:26
User entered 'None (1)'	System	02 Oct 2020 07:04:26

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '610d5591-3ca1-44f2-8dfc-e2fc9ef30a7b'	System	02 Oct 2020 07:04:26
User entered 'No (N)'	System	02 Oct 2020 07:04:26

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '610d5591-3ca1-44f2-8dfc-e2fc9ef30a7b'	System	02 Oct 2020 07:04:26
User entered 'No (N)'	System	02 Oct 2020 07:04:26

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:16', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '610d5591-3ca1-44f2-8dfc-e2fc9ef30a7b'	System	02 Oct 2020 07:04:26
User entered 'None (1)'	System	02 Oct 2020 07:04:26

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '610d5591-3ca1-44f2-8dfc-e2fc9ef30a7b'	System	02 Oct 2020 07:04:26
User entered '02 Oct 2020 02:04'	System	02 Oct 2020 07:04:26

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 7'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

FDA-CBER-2022-1614-1649559

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
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)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:28:14
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:37:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'None (0)'	System	26 Sep 2020 17:39:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:38:51', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered 'No (N)'	System	26 Sep 2020 17:39:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-26T12:39:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '001408a8-83f7-45a7-851f-704bd5eba785'	System	26 Sep 2020 17:39:08
User entered '26 Sep 2020 12:39'	System	26 Sep 2020 17:39:08

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 12:24'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 14:54'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:19', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'None (0)'	System	27 Sep 2020 15:15:57

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'No interference with activity (1)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'None (0)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:38', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'None (0)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:42', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'None (0)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'None (0)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered 'No (N)'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T10:15:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '59d3c0bc-f0f5-4dc8-b633-735601f9bd07'	System	27 Sep 2020 15:15:57
User entered '27 Sep 2020 10:15'	System	27 Sep 2020 15:15:57

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '26 Sep 2020 15:49'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 2'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:36', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'None (0)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered 'No (N)'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-27T18:57:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3ad0550f-96fe-4df5-b301-0ebdc9f2702b'	System	27 Sep 2020 23:58:03
User entered '27 Sep 2020 18:57'	System	27 Sep 2020 23:58:03

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 3'	System	26 Sep 2020 17:09:35

FDA-CBER-2022-1614-1649600

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 4'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:47', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:56', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:08:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'None (0)'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:09:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered 'No (N)'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-29T22:09:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5179b170-9dc0-49e3-8b55-502d4c94289b'	System	30 Sep 2020 03:09:08
User entered '29 Sep 2020 22:09'	System	30 Sep 2020 03:09:08

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 5'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:43', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:46', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:49', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:51', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'None (0)'	System	01 Oct 2020 02:03:05

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:02:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered 'No (N)'	System	01 Oct 2020 02:03:05

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-09-30T21:03:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bc3c278e-80b2-41a1-9f93-8c123f9936f9'	System	01 Oct 2020 02:03:05
User entered '30 Sep 2020 21:03'	System	01 Oct 2020 02:03:05

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 6'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:35', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:50', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'None (0)'	System	02 Oct 2020 07:05:07

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:04:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered 'No (N)'	System	02 Oct 2020 07:05:07

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-02T02:05:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1fc9c4d-431f-4db7-b18c-08b05cc8f29e'	System	02 Oct 2020 07:05:07
User entered '02 Oct 2020 02:05'	System	02 Oct 2020 07:05:07

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:28:14
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	26 Sep 2020 17:09:35
User entered 'Day 7'	System	26 Sep 2020 17:09:35

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:28:14
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

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)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02

US3272315

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:09:35

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:09:35

US3272315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:48:44

US3272315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '05 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:48:44

US3272315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 16:48:44

US3272315

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:48:44

US3272315
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:48:48

US3272315
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:21
User entered '1'	System	12 Oct 2020 16:48:48

US3272315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:49:06

US3272315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:49:06

US3272315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 16:49:06

US3272315

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:49:06

US3272315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:49:10

US3272315

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:21
User entered '1'	System	12 Oct 2020 16:49:10

US3272315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:39:50

US3272315

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '19 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 19:39:50

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Oct 2020 19:39:50

US3272315
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 19:39:50

US3272315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:39:54

US3272315

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:09
User entered '1'	System	22 Oct 2020 19:39:54

US3272315
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:40:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 19:40:05

US3272315

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Oct 2020 19:40:05

US3272315
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered 'VISIT3'	System	22 Oct 2020 19:40:05

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

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US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '13:24'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered '22 Oct 2020 13:24'	System	22 Oct 2020 19:40:35

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '36.9' C	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '84'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered 'bpm'	System	22 Oct 2020 19:40:35

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '18'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered 'breaths/min'	System	22 Oct 2020 19:40:35

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US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '137'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered 'mmHg'	System	22 Oct 2020 19:40:35

US3272315
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '83'	(b) (4), (b) (6)	22 Oct 2020 19:40:35

US3272315

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered 'mmHg'	System	22 Oct 2020 19:40:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:40:42

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 19:40:42

FDA-CBER-2022-1614-1649695

US3272315

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:41:07

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 19:41:07

FDA-CBER-2022-1614-1649697

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '13:33'	(b) (4), (b) (6)	22 Oct 2020 19:41:07

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:28:14
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered '22 Oct 2020 13:33'	System	22 Oct 2020 19:41:07

US3272315

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 19:41:11

US3272315
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:56:02
User entered '1'	System	22 Oct 2020 19:41:11

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 64'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-23T00:02:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b07ce8f6-a2cb-41c6-b783-fea4cf0958da'	System	23 Oct 2020 05:02:25
User entered 'No (N)'	System	23 Oct 2020 05:02:25

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-23T00:02:11', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b07ce8f6-a2cb-41c6-b783-fea4cf0958da'	System	23 Oct 2020 05:02:25
User entered 'No (N)'	System	23 Oct 2020 05:02:25

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-10-23T00:02:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'b07ce8f6-a2cb-41c6-b783-fea4cf0958da'	System	23 Oct 2020 05:02:25
User entered '23 Oct 2020 00:02:20'	System	23 Oct 2020 05:02:25

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '23 Oct 2020 00:01'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '27 Oct 2020 23:59'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 71'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

FDA-CBER-2022-1614-1649711

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '30 Oct 2020 00:01'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '03 Nov 2020 23:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 78'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-11-06T10:30:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e5d7bc6d-87ef-4be5-bee3-d16af9a635c1'	System	06 Nov 2020 16:31:01
User entered 'No (N)'	System	06 Nov 2020 16:31:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-11-06T10:30:39', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e5d7bc6d-87ef-4be5-bee3-d16af9a635c1'	System	06 Nov 2020 16:31:01
User entered 'No (N)'	System	06 Nov 2020 16:31:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-11-06T10:30:55', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e5d7bc6d-87ef-4be5-bee3-d16af9a635c1'	System	06 Nov 2020 16:31:01
User entered '06 Nov 2020 10:30:55'	System	06 Nov 2020 16:31:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '06 Nov 2020 00:01'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:39:02
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '10 Nov 2020 23:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered 'Day 92'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '20 Nov 2020 00:01'	System	23 Aug 2020 17:32:01

US3272315

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:27:57
Data entry locked.	System	23 Aug 2020 17:32:01
User entered '24 Nov 2020 23:59'	System	23 Aug 2020 17:32:01

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2020-11-19T21:57:14', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1099935-50b1-4ea7-b3fb-b59ef22ab4ef'	System	20 Nov 2020 03:57:31
User entered 'No (N)'	System	20 Nov 2020 03:57:31

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2020-11-19T21:57:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1099935-50b1-4ea7-b3fb-b59ef22ab4ef'	System	20 Nov 2020 03:57:31
User entered 'No (N)'	System	20 Nov 2020 03:57:31

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-11-19T21:57:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd1099935-50b1-4ea7-b3fb-b59ef22ab4ef'	System	20 Nov 2020 03:57:31
User entered '19 Nov 2020 21:57:26'	System	20 Nov 2020 03:57:31

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 Nov 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 Nov 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2020-11-24T03:33:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e9d70ad0-7f6a-4c72-bd63-bbcfacf1bdfa'	System	24 Nov 2020 09:34:15
User entered 'No (N)'	System	24 Nov 2020 09:34:15

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2020-11-24T03:34:07', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e9d70ad0-7f6a-4c72-bd63-bbcfacf1bdfa'	System	24 Nov 2020 09:34:15
User entered 'No (N)'	System	24 Nov 2020 09:34:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-11-24T03:34:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'e9d70ad0-7f6a-4c72-bd63-bbcfacf1bdfa'	System	24 Nov 2020 09:34:15
User entered '24 Nov 2020 03:34:12'	System	24 Nov 2020 09:34:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 Nov 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 Nov 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2020-12-01T08:00:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a669adb3-c88f-4fa5-bfcf-13f55c389c94'	System	01 Dec 2020 14:00:36
User entered 'No (N)'	System	01 Dec 2020 14:00:36

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2020-12-01T08:00:26', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a669adb3-c88f-4fa5-bfcf-13f55c389c94'	System	01 Dec 2020 14:00:36
User entered 'No (N)'	System	01 Dec 2020 14:00:36

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-12-01T08:00:33', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'a669adb3-c88f-4fa5-bfcf-13f55c389c94'	System	01 Dec 2020 14:00:36
User entered '01 Dec 2020 08:00:33'	System	01 Dec 2020 14:00:36

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Dec 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Dec 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Dec 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Dec 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2020-12-18T16:34:57', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bd62a43a-355e-45c6-a6b4-7e42caa72147'	System	18 Dec 2020 22:35:12
User entered 'No (N)'	System	18 Dec 2020 22:35:12

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2020-12-18T16:35:02', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bd62a43a-355e-45c6-a6b4-7e42caa72147'	System	18 Dec 2020 22:35:12
User entered 'No (N)'	System	18 Dec 2020 22:35:12

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-12-18T16:35:06', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'bd62a43a-355e-45c6-a6b4-7e42caa72147'	System	18 Dec 2020 22:35:12
User entered '18 Dec 2020 16:35:06'	System	18 Dec 2020 22:35:12

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Dec 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Dec 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2020-12-22T12:26:04', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3a44cb78-5fd8-47c4-9c91-cecf029ded5a'	System	22 Dec 2020 18:26:17
User entered 'No (N)'	System	22 Dec 2020 18:26:17

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2020-12-22T12:26:09', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3a44cb78-5fd8-47c4-9c91-cecf029ded5a'	System	22 Dec 2020 18:26:17
User entered 'No (N)'	System	22 Dec 2020 18:26:17

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2020-12-22T12:26:12', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '3a44cb78-5fd8-47c4-9c91-cecf029ded5a'	System	22 Dec 2020 18:26:17
User entered '22 Dec 2020 12:26:12'	System	22 Dec 2020 18:26:17

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Dec 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Dec 2020 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-01-02T04:24:24', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '636d9cfa-02d2-46ef-88b1-3e962dbc3317'	System	02 Jan 2021 11:24:40
User entered 'No (N)'	System	02 Jan 2021 11:24:40

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-01-02T04:24:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '636d9cfa-02d2-46ef-88b1-3e962dbc3317'	System	02 Jan 2021 11:24:40
User entered 'No (N)'	System	02 Jan 2021 11:24:40

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-01-02T04:24:37', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '636d9cfa-02d2-46ef-88b1-3e962dbc3317'	System	02 Jan 2021 11:24:40
User entered '02 Jan 2021 04:24:37'	System	02 Jan 2021 11:24:40

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 Dec 2020 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Jan 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-01-05T01:01:54', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd3118dc-937d-45c1-b870-a41926095d14'	System	05 Jan 2021 07:02:21
User entered 'No (N)'	System	05 Jan 2021 07:02:21

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-01-05T01:02:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd3118dc-937d-45c1-b870-a41926095d14'	System	05 Jan 2021 07:02:21
User entered 'No (N)'	System	05 Jan 2021 07:02:21

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-01-05T01:02:17', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'fd3118dc-937d-45c1-b870-a41926095d14'	System	05 Jan 2021 07:02:21
User entered '05 Jan 2021 01:02:17'	System	05 Jan 2021 07:02:21

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Jan 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Jan 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-01-15T20:57:20', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '06655e57-820a-466c-ab51-6a2b31400ea6'	System	16 Jan 2021 02:57:34
User entered 'No (N)'	System	16 Jan 2021 02:57:34

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-01-15T20:57:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '06655e57-820a-466c-ab51-6a2b31400ea6'	System	16 Jan 2021 02:57:34
User entered 'No (N)'	System	16 Jan 2021 02:57:34

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-01-15T20:57:31', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '06655e57-820a-466c-ab51-6a2b31400ea6'	System	16 Jan 2021 02:57:34
User entered '15 Jan 2021 20:57:31'	System	16 Jan 2021 02:57:34

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Jan 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Jan 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-01-19T01:43:52', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'becd4d8e-37eb-4377-a5f6-3e462c7cf1c9'	System	19 Jan 2021 07:44:04
User entered 'No (N)'	System	19 Jan 2021 07:44:04

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-01-19T01:43:58', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'becd4d8e-37eb-4377-a5f6-3e462c7cf1c9'	System	19 Jan 2021 07:44:04
User entered 'No (N)'	System	19 Jan 2021 07:44:04

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-01-19T01:44:01', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'becd4d8e-37eb-4377-a5f6-3e462c7cf1c9'	System	19 Jan 2021 07:44:04
User entered '19 Jan 2021 01:44:01'	System	19 Jan 2021 07:44:04

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Jan 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Jan 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-01-26T00:02:15', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f04b4f1e-c198-4400-90a8-2ada88b9b033'	System	26 Jan 2021 06:02:29
User entered 'No (N)'	System	26 Jan 2021 06:02:29

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-01-26T00:02:22', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f04b4f1e-c198-4400-90a8-2ada88b9b033'	System	26 Jan 2021 06:02:29
User entered 'No (N)'	System	26 Jan 2021 06:02:29

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-01-26T00:02:25', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'f04b4f1e-c198-4400-90a8-2ada88b9b033'	System	26 Jan 2021 06:02:29
User entered '26 Jan 2021 00:02:25'	System	26 Jan 2021 06:02:29

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Jan 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Jan 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-05T18:11:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '223050db-014f-412f-bab2-5e980a9995e0'	System	06 Feb 2021 00:12:08
User entered 'No (N)'	System	06 Feb 2021 00:12:08

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-02-05T18:11:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '223050db-014f-412f-bab2-5e980a9995e0'	System	06 Feb 2021 00:12:08
User entered 'No (N)'	System	06 Feb 2021 00:12:08

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-05T18:12:03', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '223050db-014f-412f-bab2-5e980a9995e0'	System	06 Feb 2021 00:12:08
User entered '05 Feb 2021 18:12:03'	System	06 Feb 2021 00:12:08

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Feb 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Feb 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-11T12:19:53', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'Yes (Y)'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-02-11T12:19:59', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'No (N)'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-11T12:20:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'Yes (Y)'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '1'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '1'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:23', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '0'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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 (c41544c53796a89f)', Time: '2021-02-11T12:20:30', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-11T12:20:34', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'Yes (Y)'	System	11 Feb 2021 18:20:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Please 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 (c41544c53796a89f)', Time: '2021-02-11T12:20:40', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-11T12:20:44', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '9bafe3f2-d7f1-417d-b475-c58dd28f0dcb'	System	11 Feb 2021 18:20:57
User entered '11 Feb 2021 12:20:44'	System	11 Feb 2021 18:20:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Feb 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Feb 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-19T17:13:10', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '16d65d7f-3d02-439c-8c6b-4cf9002773d4'	System	19 Feb 2021 23:17:09
User entered 'No (N)'	System	19 Feb 2021 23:17:09

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-02-19T17:13:14', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '16d65d7f-3d02-439c-8c6b-4cf9002773d4'	System	19 Feb 2021 23:17:09
User entered 'No (N)'	System	19 Feb 2021 23:17:09

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-19T17:13:18', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '16d65d7f-3d02-439c-8c6b-4cf9002773d4'	System	19 Feb 2021 23:17:09
User entered '19 Feb 2021 17:13:18'	System	19 Feb 2021 23:17:09

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Feb 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Feb 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (c41544c53796a89f)', Time: '2021-02-25T12:02:38-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '17cac910-0465-4c11-b483-c2549db2a46b'	System	25 Feb 2021 18:07:01
User entered 'No (N)'	System	25 Feb 2021 18:07:01

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (c41544c53796a89f)', Time: '2021-02-25T12:02:45-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '17cac910-0465-4c11-b483-c2549db2a46b'	System	25 Feb 2021 18:07:01
User entered 'No (N)'	System	25 Feb 2021 18:07:01

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c41544c53796a89f)', Time: '2021-02-25T12:02:50-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '17cac910-0465-4c11-b483-c2549db2a46b'	System	25 Feb 2021 18:07:01
User entered '25 Feb 2021 12:02:50'	System	25 Feb 2021 18:07:01

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Feb 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Feb 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Mar 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Mar 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-03-12T14:09:27-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5648e55f-1209-4fd4-be34-95c5e1a17dab'	System	12 Mar 2021 20:09:46
User entered 'No (N)'	System	12 Mar 2021 20:09:46

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-03-12T14:09:33-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5648e55f-1209-4fd4-be34-95c5e1a17dab'	System	12 Mar 2021 20:09:46
User entered 'No (N)'	System	12 Mar 2021 20:09:46

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-03-12T14:09:38-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5648e55f-1209-4fd4-be34-95c5e1a17dab'	System	12 Mar 2021 20:09:46
User entered '12 Mar 2021 14:09:38'	System	12 Mar 2021 20:09:46

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Mar 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Mar 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-03-16T00:01:45-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '22f33bb6-51b6-41f2-ad34-af96551019ce'	System	16 Mar 2021 05:01:55
User entered 'No (N)'	System	16 Mar 2021 05:01:55

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-03-16T00:01:49-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '22f33bb6-51b6-41f2-ad34-af96551019ce'	System	16 Mar 2021 05:01:55
User entered 'No (N)'	System	16 Mar 2021 05:01:55

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-03-16T00:01:52-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '22f33bb6-51b6-41f2-ad34-af96551019ce'	System	16 Mar 2021 05:01:55
User entered '16 Mar 2021 00:01:52'	System	16 Mar 2021 05:01:55

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Mar 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Mar 2021 23:59'	System	20 Nov 2020 01:27:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:27:57

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US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-03-23T00:01:51-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd9817787-4ca8-41d7-bbee-c9a9421245a2'	System	23 Mar 2021 05:02:00
User entered 'No (N)'	System	23 Mar 2021 05:02:00

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-03-23T00:01:55-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd9817787-4ca8-41d7-bbee-c9a9421245a2'	System	23 Mar 2021 05:02:00
User entered 'No (N)'	System	23 Mar 2021 05:02:00

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-03-23T00:01:59-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'd9817787-4ca8-41d7-bbee-c9a9421245a2'	System	23 Mar 2021 05:02:00
User entered '23 Mar 2021 00:01:59'	System	23 Mar 2021 05:02:00

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Mar 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Mar 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-03T08:59:32-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered 'Yes (Y)'	System	03 Apr 2021 14:00:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-04-03T08:59:37-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered 'No (N)'	System	03 Apr 2021 14:00:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-03T08:59:42-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered 'No (N)'	System	03 Apr 2021 14:00:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-03T08:59:50-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered 'Yes (Y)'	System	03 Apr 2021 14:00:15

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Please 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 (bfb062bca3190700)', Time: '2021-04-03T08:59:58-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 14:00:15

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-04-03T09:00:04-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '5f15c423-f2aa-446c-a5c9-230e7e4bcad9'	System	03 Apr 2021 14:00:15
User entered '03 Apr 2021 09:00:04'	System	03 Apr 2021 14:00:15

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Mar 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '03 Apr 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-06T12:38:09-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'cdbfe1a1-4334-455a-9e89-fbecb0070b0f'	System	06 Apr 2021 17:38:19
User entered 'No (N)'	System	06 Apr 2021 17:38:19

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-04-06T12:38:13-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'cdbfe1a1-4334-455a-9e89-fbecb0070b0f'	System	06 Apr 2021 17:38:19
User entered 'No (N)'	System	06 Apr 2021 17:38:19

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-04-06T12:38:16-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'cdbfe1a1-4334-455a-9e89-fbecb0070b0f'	System	06 Apr 2021 17:38:19
User entered '06 Apr 2021 12:38:16'	System	06 Apr 2021 17:38:19

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Apr 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '10 Apr 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-17T16:29:37-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '64318e5e-e1c4-43de-bbd1-bc3851219113'	System	17 Apr 2021 21:29:45
User entered 'No (N)'	System	17 Apr 2021 21:29:45

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-04-17T16:29:40-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '64318e5e-e1c4-43de-bbd1-bc3851219113'	System	17 Apr 2021 21:29:45
User entered 'No (N)'	System	17 Apr 2021 21:29:45

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-04-17T16:29:43-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '64318e5e-e1c4-43de-bbd1-bc3851219113'	System	17 Apr 2021 21:29:45
User entered '17 Apr 2021 16:29:43'	System	17 Apr 2021 21:29:45

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Apr 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 Apr 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-22T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db830db2-bcb8-4ea1-a951-13c4e9dd81ac'	System	22 Apr 2021 17:00:47
User entered 'No (N)'	System	22 Apr 2021 17:00:47

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-04-22T12:00:36-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db830db2-bcb8-4ea1-a951-13c4e9dd81ac'	System	22 Apr 2021 17:00:47
User entered 'No (N)'	System	22 Apr 2021 17:00:47

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-04-22T12:00:39-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'db830db2-bcb8-4ea1-a951-13c4e9dd81ac'	System	22 Apr 2021 17:00:47
User entered '22 Apr 2021 12:00:39'	System	22 Apr 2021 17:00:47

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Apr 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 Apr 2021 23:59'	System	20 Nov 2020 01:27:57

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

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 (bfb062bca3190700)', Time: '2021-04-27T00:01:31-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2560ed74-9cce-4b1b-a79d-a709ddfb5eb6'	System	27 Apr 2021 05:01:41
User entered 'No (N)'	System	27 Apr 2021 05:01:41

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Have you been exposed to someone with 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 (bfb062bca3190700)', Time: '2021-04-27T00:01:35-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2560ed74-9cce-4b1b-a79d-a709ddfb5eb6'	System	27 Apr 2021 05:01:41
User entered 'No (N)'	System	27 Apr 2021 05:01:41

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-04-27T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: '2560ed74-9cce-4b1b-a79d-a709ddfb5eb6'	System	27 Apr 2021 05:01:41
User entered '27 Apr 2021 00:01:38'	System	27 Apr 2021 05:01:41

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Apr 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 May 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 May 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 May 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 May 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 May 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 May 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 May 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 May 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 May 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Jun 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Jun 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Jun 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Jun 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Jun 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Jun 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Jun 2021 00:01'	System	20 Nov 2020 01:27:57

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Jun 2021 23:59'	System	20 Nov 2020 01:27:57

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US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 Jun 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '03 Jul 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Jul 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '10 Jul 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Jul 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 Jul 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Jul 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 Jul 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Jul 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '31 Jul 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '03 Aug 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '07 Aug 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '10 Aug 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '14 Aug 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 Aug 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 Aug 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 Aug 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 Aug 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '31 Aug 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 Sep 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '07 Sep 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 Sep 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '14 Sep 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 Sep 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 Sep 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 Sep 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 Sep 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Oct 2021 23:59'	System	20 Nov 2020 01:27:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:27:57

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US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Oct 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Oct 2021 23:59'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Oct 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Oct 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Oct 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Oct 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Oct 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Oct 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Nov 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Nov 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Nov 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Nov 2021 23:59'	System	20 Nov 2020 01:27:57

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Nov 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Nov 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Nov 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Nov 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Nov 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 Dec 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '07 Dec 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 Dec 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:27:57

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '14 Dec 2021 00:01'	System	20 Nov 2020 01:27:57

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US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 Dec 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 Dec 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 Dec 2021 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 Dec 2021 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Jan 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 Jan 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Jan 2022 23:59'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 Jan 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Jan 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 Jan 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Jan 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 Jan 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 Jan 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Feb 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Feb 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Feb 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Feb 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Feb 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Feb 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Feb 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Feb 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Mar 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Mar 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Mar 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Mar 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Mar 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Mar 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Mar 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Mar 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 Mar 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Apr 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Apr 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Apr 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Apr 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Apr 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Apr 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Apr 2022 23:59'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Apr 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Apr 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '03 May 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '07 May 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '10 May 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '14 May 2022 23:59'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 May 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 May 2022 23:59'	System	20 Nov 2020 01:27:57

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 May 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 May 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '31 May 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 Jun 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '07 Jun 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 Jun 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '14 Jun 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 Jun 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '21 Jun 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 Jun 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '28 Jun 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Jul 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '05 Jul 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Jul 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '12 Jul 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Jul 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '19 Jul 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Jul 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '26 Jul 2022 00:01'	System	20 Nov 2020 01:27:57

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Jul 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '02 Aug 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Aug 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '09 Aug 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Aug 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '16 Aug 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Aug 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '23 Aug 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Aug 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '30 Aug 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '03 Sep 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '06 Sep 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '10 Sep 2022 23:59'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '13 Sep 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '17 Sep 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '20 Sep 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '24 Sep 2022 23:59'	System	20 Nov 2020 01:27:57

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '27 Sep 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '01 Oct 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '04 Oct 2022 00:01'	System	20 Nov 2020 01:27:57

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '08 Oct 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '11 Oct 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '15 Oct 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:27:57

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '18 Oct 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '22 Oct 2022 23:59'	System	20 Nov 2020 01:27:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:27:57

FDA-CBER-2022-1614-1650163

US3272315
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:28:14
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '25 Oct 2022 00:01'	System	20 Nov 2020 01:27:57

US3272315

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:14

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:27:57
Amendment Manager: User entered '29 Oct 2022 23:59'	System	20 Nov 2020 01:27:57

US3272315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-03-12T14:08:35-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ff10c556-fed6-4e8b-a9d6-3158c20fa7a1'	System	12 Mar 2021 20:08:47
User entered 'No (N)'	System	12 Mar 2021 20:08:47

US3272315

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:14

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:16:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfb062bca3190700)', Time: '2021-03-12T14:08:42-06:00', User OID: 'PatientReportedOutcome (US3272315)', ODM File OID: 'ff10c556-fed6-4e8b-a9d6-3158c20fa7a1'	System	12 Mar 2021 20:08:47
User entered '12 Mar 2021 14:08:42'	System	12 Mar 2021 20:08:47

US3272315
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 00:42:57

US3272315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 00:42:57

US3272315
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 00:42:57

US3272315

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 00:42:57

US3272315

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 00:43:04

US3272315
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:43
User entered '1'	System	19 Nov 2020 00:43:04

US3272315
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:30:35
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:48:16
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 08JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM).		08 Feb 2021 16:01:08
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Dec 2020 23:27:34
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Dec 2020 23:26:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 23:26:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Dec 2020 23:27:34
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 23:27:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Dec 2020 23:26:55
User entered '22 Dec ' (non-conformant).	(b) (4), (b) (6)	23 Dec 2020 23:26:55

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US3272315
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 23:27:34
User entered empty.		23 Dec 2020 23:26:55

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 23:26:55

US3272315
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 23:41:26

US3272315

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:44
User entered '1'	System	23 Dec 2020 23:41:26

US3272315
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 20:33:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 08JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:30:33
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 08JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 21:11:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 08JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).		09 Feb 2021 10:00:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 20:33:47

US3272315
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 20:33:47

US3272315

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 20:33:47

US3272315

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 20:33:51

US3272315
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:40
User entered '1'	System	02 Feb 2021 20:33:51

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:32:37

FDA-CBER-2022-1614-1650186

US3272315
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '23 Feb 2021'	(b) (4), (b) (6)	19 Mar 2021 15:32:37

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Mar 2021 15:32:37

FDA-CBER-2022-1614-1650188

US3272315
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 15:32:37

US3272315

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:32:40

Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:35
User entered '1'	System	19 Mar 2021 15:32:40

US3272315
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:32:57

US3272315
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:32:57

US3272315
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 15:32:57

US3272315
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered 'VISIT4'	System	19 Mar 2021 15:32:57

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

FDA-CBER-2022-1614-1650197

US3272315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered empty.	System	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

FDA-CBER-2022-1614-1650203

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered empty.	System	30 Mar 2021 00:19:42

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered empty.	System	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

US3272315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered empty.	System	30 Mar 2021 00:19:42

US3272315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:19:42

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered empty.	System	30 Mar 2021 00:19:42

US3272315

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13

US3272315
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13

US3272315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:33:05

US3272315

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:33:05

US3272315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:33:25

US3272315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:33:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered '13:45'	(b) (4), (b) (6)	19 Mar 2021 15:33:25

FDA-CBER-2022-1614-1650217

US3272315

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered '12 Mar 2021 13:45'	System	19 Mar 2021 15:33:25

US3272315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:33:29

US3272315

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:59:13
User entered '1'	System	19 Mar 2021 15:33:29

US3272315
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 14:20:05

US3272315

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 19:02:39
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct' (Site from System).		29 Apr 2021 14:20:11
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Apr 2021 14:20:05
User entered '28 Apr 2021'	(b) (4), (b) (6)	29 Apr 2021 14:20:05

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Apr 2021 14:20:05

FDA-CBER-2022-1614-1650223

US3272315
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 14:20:05

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 14:20:18

US3272315

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 14:20:18

US3272315

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:49:53

US3272315

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 20:49:53

US3272315

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 20:49:53

US3272315
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 20:49:53

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:43:14

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:07:35
Query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'Data corrected' (Site from DM).		08 Apr 2021 17:34:50
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:34:33
User opened query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).		08 Apr 2021 13:06:02
User entered 'AMENDMENT 5 (AMENDMENT 5)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:43:14

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:56:43

US3272315

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:14

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '1'	System	09 Feb 2021 20:56:43

US3272315
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:28:14
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '1'	System	09 Feb 2021 20:56:43

US3272315
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

FDA-CBER-2022-1614-1650243

US3272315
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered empty.	System	09 Feb 2021 21:02:49
DataPoint set to visible.	System	09 Feb 2021 20:56:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered empty.	System	09 Feb 2021 21:02:49
DataPoint set to visible.	System	09 Feb 2021 20:56:43

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User accepted default value 'Pre-Dose (PREDOSE)'		09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13:55'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '08 Jan 2021 13:55'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.7' C	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '75'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'bpm'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '16'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'breaths/min'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '136'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'mmHg'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '88'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'mmHg'	System	09 Feb 2021 21:02:49

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:28:14
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered empty.	System	09 Feb 2021 21:02:49
DataPoint set to visible.	System	09 Feb 2021 20:56:43

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User accepted default value 'Post-Dose (POSTDOSE)'		09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '15:01'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '08 Jan 2021 15:01'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.7' C	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '82'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'bpm'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '16'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'breaths/min'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '134'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'mmHg'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '82'	(b) (4), (b) (6)	09 Feb 2021 21:02:49

US3272315

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'mmHg'	System	09 Feb 2021 21:02:49

US3272315

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:03:08

US3272315

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 21:03:08

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'mRNA-1273'	System	09 Feb 2021 21:03:56
DataPoint set to visible.	System	09 Feb 2021 20:56:43

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '14:29'	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '08 Jan 2021 14:29'	System	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'ONCE'	System	09 Feb 2021 21:03:56

US3272315

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 21:03:56

US3272315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:57:12

US3272315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 20:57:12

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13:34'	(b) (4), (b) (6)	09 Feb 2021 20:57:12

FDA-CBER-2022-1614-1650297

US3272315

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '08 Jan 2021 13:34'	System	09 Feb 2021 20:57:12

US3272315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:59:18

US3272315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 20:59:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13:38'	(b) (4), (b) (6)	09 Feb 2021 20:59:18

US3272315

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:14

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '08 Jan 2021 13:38'	System	09 Feb 2021 20:59:18

US3272315

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

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 20:59:35

US3272315
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:28:14
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:32
User entered '1'	System	09 Feb 2021 20:59:35

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:05:34

US3272315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '18 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 21:05:34

US3272315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 21:05:34

US3272315

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:05:34

US3272315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:05:39

US3272315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User entered '1'	System	09 Feb 2021 21:05:39

US3272315

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:24
User entered '1'	System	09 Feb 2021 21:05:39
DataPoint set to visible.	System	09 Feb 2021 21:05:39

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:06:04

FDA-CBER-2022-1614-1650312

US3272315
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '04 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:06:04

US3272315
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 21:06:04

US3272315
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'OLD29'	System	09 Feb 2021 21:06:04

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User accepted default value 'Pre-Dose (PREDOSE)'		09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '04 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '10:55'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered '04 Feb 2021 10:55'	System	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '37.0' C	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '73'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'bpm'	System	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '18'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'breaths/min'	System	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '112'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:28:14
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'mmHg'	System	09 Feb 2021 21:08:43

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '73'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'mmHg'	System	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User accepted default value 'Post-Dose (POSTDOSE)'		09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '04 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12:26'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered '04 Feb 2021 12:26'	System	09 Feb 2021 21:08:43

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US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.6' C	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '72'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'bpm'	System	09 Feb 2021 21:08:43

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '18'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

US3272315
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:28:14
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'breaths/min'	System	09 Feb 2021 21:08:43

US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '109'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'mmHg'	System	09 Feb 2021 21:08:43

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US3272315

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '72'	(b) (4), (b) (6)	09 Feb 2021 21:08:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'mmHg'	System	09 Feb 2021 21:08:43

FDA-CBER-2022-1614-1650347

US3272315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:08:59

US3272315

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '04 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:08:59

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'mRNA-1273'	System	09 Feb 2021 21:10:18
DataPoint set to visible.	System	09 Feb 2021 21:05:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '04 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '11:51'	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:28:14

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered '04 Feb 2021 11:51'	System	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'ONCE'	System	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 21:10:18

US3272315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:10:30

US3272315

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:14
User entered '1'	System	09 Feb 2021 21:10:30

US3272315
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:34:27

US3272315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Per CDM: Safety Call OL-D36 and OL-D57 were performed on same day (12MAR2021). Kindly review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:31:15
Query 'Per CDM: Safety Call OL-D36 and OL-D57 were performed on same day (12MAR2021). Kindly review and update accordingly. Else clarify. ' answered with 'updated' (Site from DM).		19 Apr 2021 23:20:11
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Apr 2021 23:19:55
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Apr 2021 23:19:55
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 23:19:55
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Apr 2021 23:19:22
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 23:19:22
User opened query 'Per CDM: Safety Call OL-D36 and OL-D57 were performed on same day (12MAR2021). Kindly review and update accordingly. Else clarify. ' (Site from DM).		10 Apr 2021 15:06:50
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		22 Mar 2021 11:46:30

US3272315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'this data is correct' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 15:35:09
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Mar 2021 15:34:27
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:34:27

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US3272315
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:28:14
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Mar 2021 15:34:27

US3272315

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:14

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 15:34:27

US3272315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:35:14

US3272315

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:14

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:32
User entered '1'	System	19 Mar 2021 15:35:14

US3272315
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:35:35

US3272315
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:35:35

US3272315
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 15:35:35

US3272315
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:28:14
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered 'OLD57'	System	19 Mar 2021 15:35:35

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13:31'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered '12 Mar 2021 13:31'	System	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '36.6' C	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '98'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered 'bpm'	System	19 Mar 2021 15:36:01

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '16'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered 'breaths/min'	System	19 Mar 2021 15:36:01

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '99'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

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US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered 'mmHg'	System	19 Mar 2021 15:36:01

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '71'	(b) (4), (b) (6)	19 Mar 2021 15:36:01

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered 'mmHg'	System	19 Mar 2021 15:36:01

US3272315

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26

US3272315
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:28:14
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26

US3272315

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:36:13

US3272315

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:14

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:36:13

US3272315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:36:37

US3272315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '12 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:36:37

US3272315

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '13:45'	(b) (4), (b) (6)	19 Mar 2021 15:36:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:26
User entered '12 Mar 2021 13:45'	System	19 Mar 2021 15:36:37

US3272315

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:28:14

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:54
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:44:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:34:36

US3272315
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:28:14
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Otitis media serous - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:29:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:29:02
Data point term sent to Coder	System	12 Feb 2021 00:48:39
User entered 'Bilateral Serous Otitis - ears.'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '5 Feb 2021'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Mar 2021 15:37:25
User entered '00:01' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:37:25
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Mar 2021 15:37:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 15:37:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:37:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 00:48:02
User entered 'un:un' (non-conformant).	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User entered '5 Feb 2021 00:01'	System	19 Mar 2021 15:37:25
User entered empty.	System	19 Mar 2021 15:37:15
User entered '5 Feb 2021 UN:UN' (non-conformant).	System	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:38:12
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 15:38:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Mar 2021 15:38:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 15:38:12
User entered '06 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:38:12
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '00:01' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:38:12
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User entered '06 Mar 2021 00:01'	System	19 Mar 2021 15:38:12
User entered empty.	System	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'None (NONE)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

FDA-CBER-2022-1614-1650423

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '1'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

FDA-CBER-2022-1614-1650425

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:38:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:48:02

US3272315

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User entered '0'	System	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45
User entered '1'	System	12 Feb 2021 00:48:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:45

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 00:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 00:53:14
Data point term sent to Coder	System	12 Feb 2021 00:51:47
User entered 'Sinusitis'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:39:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 15:38:59
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:38:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 00:51:05
User entered 'un Feb 2021' (non-conformant).	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User entered empty.	System	12 Feb 2021 00:51:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:39:26
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '06 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:39:26
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User entered empty.	System	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Clement (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	12 Feb 2021 00:51:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'None (NONE)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

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US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '1'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 15:39:26
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Subject was seen by PCP on 08Feb2021 due to nasal congestion and cough due to the drainage. She also complains of ears feeling full. She was given antibiotics due to Diagnosis of Sinusitis and acute serous Otitis media Bilaterally.'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User entered '0'	System	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52
User entered '1'	System	12 Feb 2021 00:51:05

US3272315

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:32:52

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

AEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:08:37
User entered 'USA-US070-2021-mRNA-1273-P301000010'		19 Apr 2021 15:04:54

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 20:30:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 20:30:04
Data point term sent to Coder	System	16 Apr 2021 20:29:06
User entered 'Aortic stenosis'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Apr 2021 21:16:21
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	16 Apr 2021 21:16:21
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:16:21
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Apr 2021 20:28:14
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	16 Apr 2021 20:28:14
User entered '01 Apr 2020'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '31 Mar 2021'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '29 Mar 2021'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '01 Apr 2021'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'PV Query: For the event, aortic stenosis, please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 08 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 19:36:27
Query 'PV Query: For the event, aortic stenosis, please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 08 Jan 2021, then event occurred).' answered with 'updated' (Site from Safety).		28 Apr 2021 15:15:26
User entered 'None (NONE)' reason for change: Data Entry Error		28 Apr 2021 15:15:15
User opened query 'PV Query: For the event, aortic stenosis, please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 08 Jan 2021, then event occurred).' (Site from Safety).		26 Apr 2021 23:22:05
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

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US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
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)	03 May 2021 13:03:28
User closed query 'IQVIA Medical 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 May 2021 13:03:21
Query 'IQVIA Medical 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 'No results currently available. Will update. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:34:34
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 'No results currently available. Will update. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:34:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 23:25:24

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User opened query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 23:22:58
User entered 'Subject has long-standing history of aortic murmur, did not follow with cardiology and last echocardiogram was 15+ years ago and was negative. Reports worsening fatigue and decreased activity beginning "around a year ago," but ignored symptoms. Severe stress beginning ⬛(b) (6)⬛ ⬛(b) (6)⬛ and began noticing exercise intolerance she attributed to grief and spinal stenosis pain. ⬛(b) (6)⬛ ⬛⬛ ⬛⬛ a home with no electricity with temp -30 deg F. After emotional and physical stress noticed significant worsening of SOB and exercise intolerance culminating in syncopal episode 01MAR2021 when she sat down on the bed to catch her breath and woke up a few minutes later. Did not seek medical attention at that time due to being out of town, made f/u the next week with echo. Echo revealed severe aortic stenosis and EF 10%, referred to cardiology. Left heart catheterization 29MAR2021 revealed no blockages. TAVR 31MAR2021 with resolution of symptoms. Attending cardiac rehab. Requesting records from hospital, subject agrees.'	Whitney West (b) (4) (b) (4)	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 20:28:14

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:22:50
Data point term sent to Coder	System	16 Apr 2021 21:22:10
User entered 'Worsening of Aortic Stenosis'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '01 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '31 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:37:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 21:37:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:37:08
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:26:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:26:04
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Apr 2021 21:23:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:23:12
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Apr 2021 21:21:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 16:28:14
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:21:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. (b) (6) A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:57:44
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:23:12
User entered '1'	System	16 Apr 2021 21:21:26

US3272315

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:21:26

US3272315
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:28:14
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:32:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:32:06
Data point term sent to Coder	System	16 Apr 2021 21:31:14
User entered 'Syncope'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '01 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '01 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 16:28:14
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:30:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING ░░░░(b) (6)░░░░ (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. (b) (6) ░░░░░░░░░░ A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:55:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:30:44

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Exercise tolerance decreased, LLT: Exercise tolerance decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:46:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:46:24
Data point term sent to Coder	System	16 Apr 2021 21:36:19
User entered 'Exercise Intolerance'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '04 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:28:14
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:36:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:36:04

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:39:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:39:53
Data point term sent to Coder	System	16 Apr 2021 21:39:22
User entered 'Bilateral lower extremity edema'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

FDA-CBER-2022-1614-1650611

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '03 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:38:33

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

AEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:04:00
User entered 'USA-US070-2021-mRNA-1273-P301000010'	System	19 Apr 2021 15:01:28
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 15:01:28

US3272315
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:28:14
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure with reduced ejection fraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 10:46:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 10:46:25
Data point term sent to Coder	System	16 Apr 2021 21:45:39
User entered 'Reduced ejection fraction heart failure'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Apr 2021 18:20:56
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	19 Apr 2021 18:20:56
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Apr 2021 18:20:56
User entered '03 Mar 2021' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 18:20:56
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 21:44:47
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 21:44:47
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:28:14
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 13:32:39
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated. ' (Site from System).	Whitney West (b) (4) (b) (4)	19 Apr 2021 18:21:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 21:44:47
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '29 Mar 2021' reason for change: Per Query Resolution	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:37:29
User entered '03 Apr 2021' reason for change: Per Query Resolution	Whitney West (b) (4) (b) (4)	19 Apr 2021 18:20:56
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query ' PV Query: Please confirm hospital discharge date as the event of aortic stenosis has 01 Apr 2021 and the event of reduced ejection fraction heart failure has admit date as 03 Apr 2021 yet resolved on 31 Mar 2021. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:03:55
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).		01 May 2021 06:42:22
User closed query 'PER SAE RECON: Hospital discharge date missing. Kindly review and update once available. ' (Site from DM).		01 May 2021 06:42:09
Query ' PV Query: Please confirm hospital discharge date as the event of aortic stenosis has 01 Apr 2021 and the event of reduced ejection fraction heart failure has admit date as 03 Apr 2021 yet resolved on 31 Mar 2021. Please clarify.' answered with 'Updating. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:36:57
Query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' answered with 'Updated. ' (Site from System).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:36:51
Query 'PER SAE RECON: Hospital discharge date missing. Kindly review and update once available. ' answered with 'Updated. ' (Site from DM).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:36:42
User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	System	30 Apr 2021 19:35:31
User entered '01 Apr 2021' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:35:31
User opened query ' PV Query: Please confirm hospital discharge date as the event of aortic stenosis has 01 Apr 2021 and the event of reduced ejection fraction heart failure has admit date as 03 Apr 2021 yet resolved on 31 Mar 2021. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 23:19:14
User opened query 'PER SAE RECON: Hospital discharge date missing. Kindly review and update once available. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:58:34
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

FDA-CBER-2022-1614-1650661

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

FDA-CBER-2022-1614-1650662

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 16:28:14
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:04:09
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).		03 May 2021 13:04:03
User closed query 'PV Query; Please provide any further medications and/or treatments the subject received for events' (Site from Safety).		03 May 2021 13:04:00
Query 'PV Query; Please provide any further medications and/or treatments the subject received for events' answered with 'No results currently available. Will update. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:37:12
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 'No results currently available. Will update. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:37:09
Query 'IQVIA Medical 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 'No results currently available. Will update. ' (Site from Safety).	Whitney West (b) (4) (b) (4)	30 Apr 2021 19:37:05
User opened query 'IQVIA Medical Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 23:23:45

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
	(b) (4), (b) (6)	
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).		26 Apr 2021 23:20:47
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 ' canceled (Site from Safety).		26 Apr 2021 23:20:20
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 ' (Site from Safety).		26 Apr 2021 23:20:13
User opened query 'PV Query; Please provide any further medications and/or treatments the subject received for events' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 23:19:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING ▓▓▓ (b) (6) ▓▓▓ AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. ▓ (b) (6) ▓ ▓▓▓▓▓▓ ▓▓▓▓▓▓ ▓▓▓▓▓▓ A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:56:18
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:44:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:44:47

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:46:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 21:46:54
Data point term sent to Coder	System	16 Apr 2021 21:46:40
User entered 'Shortness of breath'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '31 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:46:30

US3272315
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:28:14
Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:21:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:21:49
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 18:21:49
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:46:30
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 18:21:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 18:21:49
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 18:21:49
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 21:46:30
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 16:28:14
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

FDA-CBER-2022-1614-1650701

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. (b) (6) A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:55:20
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:46:30

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US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 18:21:49

US3272315

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:46:30

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Otitis media - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:25:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:25:32
Data point term sent to Coder	System	16 Apr 2021 21:51:41
User entered 'Serious Otitis Media Bilaterally'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '05 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 21:50:08
User entered '09:00' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 21:50:08
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Apr 2021 21:50:55
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered '05 Feb 2021 09:00'	System	19 Apr 2021 21:50:08
User entered empty.	System	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '06 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 21:50:08
User entered '21:00' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 21:50:08
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Apr 2021 21:50:55
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered '06 Mar 2021 21:00'	System	19 Apr 2021 21:50:08
User entered empty.	System	16 Apr 2021 21:50:55

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US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

FDA-CBER-2022-1614-1650728

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 16:28:14
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:45:47
User entered 'Not Applicable (NOT APPLICABLE)'		16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty; reason for change Data Entry Error	Whitney West (b) (4) (b) (4)	19 Apr 2021 21:50:26
User entered 'SUBJECT HAS LONG-STANDING HISTORY OF AORTIC MURMUR, DID NOT FOLLOW WITH CARDIOLOGY AND LAST ECHOCARDIOGRAM WAS 15+ YEARS AGO AND WAS NEGATIVE. REPORTS WORSENING FATIGUE AND DECREASED ACTIVITY BEGINNING "AROUND A YEAR AGO," BUT IGNORED SYMPTOMS. SEVERE STRESS BEGINNING (b) (6) (b) (6) AND BEGAN NOTICING EXERCISE INTOLERANCE SHE ATTRIBUTED TO GRIEF AND SPINAL STENOSIS PAIN. (b) (6) A HOME WITH NO ELECTRICITY WITH TEMP -30 DEG F. AFTER EMOTIONAL AND PHYSICAL STRESS NOTICED SIGNIFICANT WORSENING OF SOB AND EXERCISE INTOLERANCE CULMINATING IN SYNCOPAL EPISODE 01MAR2021 WHEN SHE SAT DOWN ON THE BED TO CATCH HER BREATH AND WOKE UP A FEW MINUTES LATER. DID NOT SEEK MEDICAL ATTENTION AT THAT TIME DUE TO BEING OUT OF TOWN, MADE F/U THE NEXT WEEK WITH ECHO. ECHO REVEALED SEVERE AORTIC STENOSIS AND EF 10%, REFERRED TO CARDIOLOGY. LEFT HEART CATHETERIZATION 29MAR2021 REVEALED NO BLOCKAGES. TAVR 31MAR2021 WITH RESOLUTION OF SYMPTOMS. ATTENDING CARDIAC REHAB. REQUESTING RECORDS FROM HOSPITAL, SUBJECT AGREES.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 21:56:34
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 21:50:55

US3272315

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 21:50:55

US3272315
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 16:28:14
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:50:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:50:34
Data point term sent to Coder	System	21 Apr 2021 20:49:04
User entered 'Shortness of breath'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

FDA-CBER-2022-1614-1650750

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:48:12

US3272315
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:48:12

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 16:28:14
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

FDA-CBER-2022-1614-1650768

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

FDA-CBER-2022-1614-1650769

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:48:12

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:30:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:30:57
Data point term sent to Coder	System	21 Apr 2021 20:50:06
User entered 'Edema, bilateral toes, right hand, 4th finger'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

FDA-CBER-2022-1614-1650784

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '12 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:49:33

US3272315
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 16:28:14
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '15 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Severity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

FDA-CBER-2022-1614-1650794

US3272315
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 16:28:14
Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 16:28:14
None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 16:28:14
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 20:49:33

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 20:49:33

US3272315

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:49:33

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:54
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per CDM: Please update medication for Dairy Dose 1 Day 27' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 11:20:05
Query 'Per CDM: Please update medication for Dairy Dose 1 Day 27' answered with 'Medication take is Tylenol, already taking and listed in con meds' (Site from DM).		20 Nov 2020 16:41:52
User opened query 'Per CDM: Please update medication for Dairy Dose 1 Day 27' (Site from DM).		10 Nov 2020 08:22:25
User entered 'Yes (Y)'		25 Aug 2020 15:35:06

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:37:34
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 Aug 2020 15:37:34
Data point term sent to Coder	System	25 Aug 2020 15:36:10
User entered 'levothyroxine'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'hypothyroidism'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '25'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:07:17
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:30:25
User entered 'Other (OTHER)' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:30:19
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:30:59
User entered 'mg (mg)'		25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mcg' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:30:19
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:36:08

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:15:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:15:35
Data point term sent to Coder	System	18 Sep 2020 19:31:28
Coding entries removed.	Ashley Bell (b) (4)	18 Sep 2020 19:31:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:37:35
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 Aug 2020 15:37:35
Data point term sent to Coder	System	25 Aug 2020 15:37:11
User entered 'metformin'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:33:26
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:31:05
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:31:00
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:32:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'DIABETES MELLITUS (TYPE 2)' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:31:00
User entered 'type 2 diabtes'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '500'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2000'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:36:42

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:32:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:32:37
Data point term sent to Coder	System	18 Sep 2020 19:31:29
Coding entries removed.	Ashley Bell (b) (4)	18 Sep 2020 19:31:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:38:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:38:39
Data point term sent to Coder	System	25 Aug 2020 15:38:12
User entered 'glipizide'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'DIABETES MELLITUS (TYPE 2)' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:31:14
User entered 'type 2 diabetes'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '5'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:37:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 15:37:36

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US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:37:36

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:13:43
Data point term sent to Coder	System	18 Sep 2020 22:48:58
Coding entries removed.	(b) (4), (b) (6)	18 Sep 2020 22:48:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:46:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:46:40
Data point term sent to Coder	System	18 Sep 2020 22:45:55
Coding entries removed.	(b) (4), (b) (6)	18 Sep 2020 22:44:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 16:26:42
Data point term sent to Coder	System	25 Aug 2020 15:39:16

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US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User entered 'meloxicam'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:13:27
Query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).		18 Sep 2020 22:48:56
User entered 'SPINAL STENOSIS (lumbar region)' reason for change: Data Entry Error		18 Sep 2020 22:48:23
User entered 'SPINAL STEnOSIS' reason for change: Data Entry Error		18 Sep 2020 22:44:57
User opened query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).		18 Sep 2020 07:31:40
User entered 'spinal steosis'		25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '7.5'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

FDA-CBER-2022-1614-1650876

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 16:28:14
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2018'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:38:31

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:51:44
Data point term sent to Coder	System	18 Sep 2020 22:49:59
Coding entries removed.	(b) (4), (b) (6)	18 Sep 2020 22:49:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 11:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 11:28:47
Data point term sent to Coder	System	25 Aug 2020 15:39:18
User entered 'flexeril'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:14:39
Query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).		18 Sep 2020 22:50:08
User entered 'SPINAL STENOSIS (lumbar region)' reason for change: Data Entry Error		18 Sep 2020 22:49:57
User opened query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).		18 Sep 2020 07:29:48
User entered 'spinal stenosis'		25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '10'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2017'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:39:10

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:40
Data point term sent to Coder	System	18 Sep 2020 19:33:38
Coding entries removed.	Ashley Bell (b) (4)	18 Sep 2020 19:33:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:41:36
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 Aug 2020 15:41:36
Data point term sent to Coder	System	25 Aug 2020 15:40:19
User entered 'lisinopril'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:26:41
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'data is correct per patient' (Site from DM).	(b) (4), (b) (6)	Nov 2020 18:00:52
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).		Nov 2020 08:45:58
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).		Nov 2020 12:15:23
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:33:37
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:33:31
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:31:15

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User entered 'type 2 diabetes'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '5'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2010'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:39:43

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:39:43

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:41:36
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 Aug 2020 15:41:36
Data point term sent to Coder	System	25 Aug 2020 15:40:19
User entered 'simvastatin'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'hyperlipidemia'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '10'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 2010'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:40:19

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:40:19

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:40:19

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:51:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:51:44
Data point term sent to Coder	System	18 Sep 2020 22:50:59
Coding entries removed.	(b) (4), (b) (6)	18 Sep 2020 22:50:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 15:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:43:41
Data point term sent to Coder	System	25 Aug 2020 15:42:21
Data point term sent to Coder	System	25 Aug 2020 15:41:20
User entered 'tylenol'	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:41:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:15:46
Query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).		18 Sep 2020 22:50:52
User entered 'SPINAL STENOSIS (lumbar region)' reason for change: Data Entry Error		18 Sep 2020 22:50:41
User opened query 'Per DM CLR: Please update the indication to reflect the specific level of ths spine affected (e.g., C2, L1, etc). Please reconcile with the Med History eCRFs as appropriate. ' (Site from DM).		18 Sep 2020 07:32:59
User entered 'SpINAL STENOSIS' reason for change: Data Entry Error		25 Aug 2020 15:41:27
User entered 'sinal stenosis'		25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '500'	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:41:27
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:41:27
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Aug 2020 15:41:27
User entered 'un UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:41:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 15:41:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:41:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:41:03
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 15:41:27
User entered empty.	System	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:41:27
User entered empty.	System	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:41:27
User entered empty.	System	25 Aug 2020 15:41:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Per DM CLR: Please note that the medication could not be verified as entered. Review and update to record a Brand or Generic Name as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:35:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:35:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:35:41
Data point term sent to Coder	System	18 Sep 2020 19:34:41
Query 'Per DM CLR: Please note that the medication could not be verified as entered. Review and update to record a Brand or Generic Name as appropriate. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	18 Sep 2020 19:34:10
Coding entries removed.	Ashley Bell (b) (4)	18 Sep 2020 19:34:04
User entered 'Prilosec' reason for change: Data Entry Error	Ashley Bell (b) (4)	18 Sep 2020 19:34:04
User opened query 'Per DM CLR: Please note that the medication could not be verified as entered. Review and update to record a Brand or Generic Name as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:32:41

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User		Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	02 Sep 2020 12:17:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	02 Sep 2020 12:17:42
Data point term sent to Coder	System		25 Aug 2020 15:42:22
User entered 'prilosol'	(b) (4), (b) (6)		25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '10'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:41:57

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:41:57

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:32:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:32:08
Data point term sent to Coder	System	12 Feb 2021 00:54:48
User entered 'Prednisone'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

FDA-CBER-2022-1614-1650982

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Sinusitis and SOM Bilaterally'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '30'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'once daily (QD)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '8 Feb 2021'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:59
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Feb 2021 00:54:59
User entered empty; reason for change Data Entry Error	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:59
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	12 Feb 2021 00:54:03
User entered '12 Feb 2021'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 00:54:03

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 09:35:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 09:35:04
Data point term sent to Coder	System	12 Feb 2021 00:56:49
User entered 'Doxycycline'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Sinusitis and SOM Bilaterally'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '100'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'mg (mg)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'twice daily (BID)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Oral (ORAL)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '8 Feb 2021'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 00:56:16

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
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)	28 Apr 2021 15:29:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:29:52
Data point term sent to Coder	System	28 Apr 2021 14:59:13
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Influenza Prophylaxis'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0.5'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'mL (mL)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '10 Nov 2020'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '10 Nov 2020'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User entered empty.	System	28 Apr 2021 14:59:09

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User entered empty.	System	28 Apr 2021 14:59:09

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US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:21
User entered empty.	System	28 Apr 2021 14:59:09

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:55:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:55:08
Data point term sent to Coder	System	28 Apr 2021 15:01:20
User entered 'Lasix'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Worsening of aortic stenosis'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '40'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:00:49

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '19 Mar 2021'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 15:00:49

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
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)	28 Apr 2021 15:32:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:32:49
Data point term sent to Coder	System	28 Apr 2021 15:02:21
User entered 'Aspirin'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Cardiac health'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

FDA-CBER-2022-1614-1651056

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 15:02:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 15:02:17
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 15:02:17
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 15:01:51
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 15:02:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Apr 2021 15:02:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 15:02:17
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Apr 2021 15:01:51
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 15:02:17
User entered empty.		28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '01 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 15:01:51

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 15:33:40
Data point term sent to Coder	System	28 Apr 2021 15:03:23
User entered 'Coreg'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Worsening of aortic stenosis'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'UNK'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'UNK'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:03:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

FDA-CBER-2022-1614-1651080

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '01 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:03:12

FDA-CBER-2022-1614-1651085

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:14

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 15:03:12

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:28:14

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 15:22:53
User entered 'Yes (Y)' reason for change: Data Entry Error		28 Apr 2021 15:22:53
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:11:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:34:32

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:14

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '31 Mar 2021'	(b) (4), (b) (6)	28 Apr 2021 15:23:34

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:14

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Transcatheter aortic valve replacement'	(b) (4), (b) (6)	28 Apr 2021 15:23:34

FDA-CBER-2022-1614-1651092

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	28 Apr 2021 15:23:34

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:23:34

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '29 Mar 2021'	(b) (4), (b) (6)	28 Apr 2021 15:24:20

FDA-CBER-2022-1614-1651095

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:14

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Left heart catheterization'	(b) (4), (b) (6)	28 Apr 2021 15:24:20

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:14

Indication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	28 Apr 2021 15:24:20

US3272315

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 15:24:20

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'USA-US070-2021-MRNA-1273-P301000010'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Adam'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651107

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Brosz'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '2444 W. Faidley Ave'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Grand Island'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'NE'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '68803'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 19:38:22
User entered 'US'	System	19 Apr 2021 15:32:03

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:55:02
User entered '3'	System	28 Apr 2021 19:38:33
User entered '2'	System	20 Apr 2021 13:12:08
User entered '1'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'USA-US070-2021-MRNA-1273-P301000010'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Adam'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651123

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Brosz'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651124

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '2444 W. Faidley Ave'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Grand Island'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'NE'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '68803'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 19:38:22
User entered 'US'	System	19 Apr 2021 15:32:03

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:55:02
User entered '3'	System	28 Apr 2021 19:38:33
User entered '2'	System	20 Apr 2021 13:12:08
User entered '1'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '19/Apr/2021 11:32'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 12:54:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 15:32:03

FDA-CBER-2022-1614-1651132

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'USA-US070-2021-MRNA-1273-P301000010'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651137

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Adam'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Brosz'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '2444 W. Faidley Ave'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Grand Island'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'NE'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '68803'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 19:38:22
User entered 'US'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:55:02
User entered '3'	System	28 Apr 2021 19:38:33
User entered '2'	System	20 Apr 2021 13:12:08
User entered '1'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '20/Apr/2021 06:12'	System	20 Apr 2021 13:12:08

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 12:54:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 13:12:08

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'USA-US070-2021-MRNA-1273-P301000010'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651153

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Adam'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Brosz'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '2444 W. Faidley Ave'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Grand Island'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'NE'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '68803'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 19:38:22
User entered 'US'	System	19 Apr 2021 15:32:03

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:55:02
User entered '3'	System	28 Apr 2021 19:38:33
User entered '2'	System	20 Apr 2021 13:12:08
User entered '1'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:14

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '28/Apr/2021 15:38'	System	28 Apr 2021 19:38:33

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 12:54:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
User entered '1'	(b) (4), (b) (6)	28 Apr 2021 19:38:33

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'USA-US070-2021-MRNA-1273-P301000010'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Death

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Yes (Y)'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651175

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'No (N)'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651176

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Adam'	System	19 Apr 2021 15:01:28

FDA-CBER-2022-1614-1651177

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Brosz'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '2444 W. Faidley Ave'	System	19 Apr 2021 15:01:28

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 16:28:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'Grand Island'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered 'NE'	System	19 Apr 2021 15:01:28

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:31:55
User entered '68803'	System	19 Apr 2021 15:01:28

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:47:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 19:38:22
User entered 'US'	System	19 Apr 2021 15:32:03

US3272315

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:14

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:55:02
User entered '3'	System	28 Apr 2021 19:38:33
User entered '2'	System	20 Apr 2021 13:12:08
User entered '1'	System	19 Apr 2021 15:32:03

US3272315
Folder: SAE USA-US070-2021-MRNA-1273-P301000010
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:28:14
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '03/May/2021 05:55'	System	03 May 2021 12:55:02

Folder: SAE USA-US070-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:28:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:39
User entered '1'	(b) (4), (b) (6)	03 May 2021 12:55:02