US3272031 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:22:39

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US3272031

Form: Participant Creation

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Participant ID	US3272031

mRNA-1273-P301 Completion Guidelines

US3272031

Folder: Screening

Form: Visit Date

Data signed: [(b) (4)] **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	01 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3272031

Folder: Screening

Form: Demographics

Data signed: [(b) (4)] **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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

US3272031

Folder: Screening

Form: Enrollment

Data signed: [(b) (4)] **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Date of Informed Consent *(dd MMM yyyy)*	01 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

Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **29 Apr 2021 16:58:05**
Generated On: 09 Jun 2021 16:22:39

Did the participant meet all eligibility criteria?   Yes ●

No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Were any significant conditions reported?   Yes ●

No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	TOTAL RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	06 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	06 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	TOTAL LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN OCT 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬭
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2016
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	OCT 2016
Stop Year (derived)	2016

US3272031

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3272031

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ⚪
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	LICHEN SCLEROSUS BILATERAL LOWER EXTREMITIES
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)	

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	ORAL HERPES SIMPLEX 1
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)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1612210

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	15 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1612211

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	GRAVES DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1612213

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	SEASONAL ALLERGIES
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)	

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4)   **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	BILATERAL KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	06 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	TYPE 2 DIABETES
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)	

Folder: Screening

Form: Medical History (16)

Data signed: ░░░░ (b) (4) ░░░░ **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	SEVERE OBESITY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4)   **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) **29 Apr 2021 16:58:05**

Generated On: 09 Jun 2021 16:22:39

Condition	MAMMOGRAM
Start date (dd MMM yyyy)	28 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	28 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

FDA-CBER-2022-1614-1612219

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	01 AUG 2020
Time of assessment *(00:00-23:59)*	12:46 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 12:46
Height *(xxx.x)*	175.0 cm
Weight *(xxx.x)*	123.0 kg
BMI *(xxx.x)*	40.16327 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

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

| Date of examination *(dd MMM yyyy)* | 01 AUG 2020 |

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Date of assessment *(dd MMM yyyy)*	1 AUG 2020
Is the participant of childbearing potential?	Yes ⚪
	No ⚫
If No, what is the reason?	Surgically sterile ⚪
	Post-menopausal ⚫
	Partner medically sterile ⚪
	Not reached age of Menarche ⚪
	Other ⚪
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 2002
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Data signed: [(b) (4)] **29 Apr 2021 16:58:06**

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Occupational Risk

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

Location and Living Circumstances Risk (check all that apply)

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

Folder: Screening
Form: Risk of Exposure
Data signed: [(b) (4)] **29 Apr 2021 16:58:06**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

Data signed: (b) (4) **29 Apr 2021 16:58:06**
Generated On: 09 Jun 2021 16:22:39

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	01 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: [b] (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

What was the date of randomization? *(dd MMM yyyy)*	01 AUG 2020
What was the participant's randomization number?	184340

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

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

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

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)*	01 AUG 2020
Time of assessment *(00:00-23:59)*	12:46 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 12:46
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

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)*	01 AUG 2020
Time of assessment *(00:00-23:59)*	14:39 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 14:39
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ◯
	Axillary ◯
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was the physical examination performed? Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)* 01 AUG 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)*	01 AUG 2020
What was the treatment time? *(00:00-23:59)*	14:09 (24 HR)
Treatment Date and Time (derived)	01 AUG 2020 14:09

Which arm was used to give treatment?

Left Arm ⬤

Right Arm ◯

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

| Was the sample collected? | Yes ⬤ |
| | No ◯ |

Collection date *(dd MMM yyyy)*	01 AUG 2020
Collection time *(00:00-23:59)*	13:26 (24 HR)
Collection date and time (derived)	01 AUG 2020 13:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*			01 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:11	01 AUG 2020 13:11
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ●

                                                     No ○

Continuing Flag   1

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

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

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

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

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

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

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

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

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

PC Time Stamp	01 AUG 2020 14:52
PC Open Date & Time	01 AUG 2020 14:29
PC Close Date & Time	01 AUG 2020 16:59

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**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	01 AUG 2020 18:02
PC Open Date & Time	01 AUG 2020 17:54
PC Close Date & Time	02 AUG 2020 11:59

FDA-CBER-2022-1614-1612236

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:22:39

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**	96.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	02 AUG 2020 16:04
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:22:39

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

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

PC Time Stamp	03 AUG 2020 15:01
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

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**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	04 AUG 2020 15:30
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:22:39

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**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	05 AUG 2020 14:46
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-1612240

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:22:39

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**	96.3 °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	06 AUG 2020 13:53
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:22:39

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**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	07 AUG 2020 14:17
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	01 AUG 2020 14:53
PC Open Date & Time	01 AUG 2020 14:29
PC Close Date & Time	01 AUG 2020 16:59

FDA-CBER-2022-1614-1612243

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	01 AUG 2020 18:02
PC Open Date & Time	01 AUG 2020 17:54
PC Close Date & Time	02 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:22:39

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	02 AUG 2020 16:05
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

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	03 AUG 2020 15:02
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

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	04 AUG 2020 15:30
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 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	05 AUG 2020 14:47
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 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	06 AUG 2020 13:53
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	07 AUG 2020 14:17
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:22:39

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 ○

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:22:39

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	01 AUG 2020 14:54
PC Open Date & Time	01 AUG 2020 14:29
PC Close Date & Time	01 AUG 2020 16:59

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	01 AUG 2020 18:03
PC Open Date & Time	01 AUG 2020 17:54
PC Close Date & Time	02 AUG 2020 11:59

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:22:39

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	02 AUG 2020 16:06
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

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 ●

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Yes ◯

PC Time stamp	03 AUG 2020 15:03
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:22:39

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	04 AUG 2020 15:31
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:22:39

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	05 AUG 2020 14:48
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39

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	06 AUG 2020 13:54
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

TIMEPOINT	DAY 7
HEADACHE	None ⬤
	No interference with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
FATIGUE	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
MUSCLE ACHES ALL OVER BODY	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
JOINT ACHES IN SEVERAL JOINTS	None ⬤
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
NAUSEA/VOMITING	None ⬤
	No interference with activity or 1-2 episodes/24 hours ◯
	Some interference with activity or >2 episodes/24 hours ◯
	Prevents daily activity, requires outpatient IV hydration ◯
CHILLS	None ⬤
	No interference with activity ◯
	Some interference with activity not requiring medical attention ◯
	Prevents daily activity and requires medical attention ◯
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤

	Yes ◯
PC Time stamp	07 AUG 2020 14:18
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 10 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 17 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ⬭

Continuing Flag   1

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments _____

US3272031

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: ░░░░ (b) (4) ░░░░ **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3272031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT2

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	01 SEP 2020
Time of assessment *(00:00-23:59)*	12:10 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:10
Temperature *(xxx.x)*	37.3 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Timepoint	Pre-Dose ◯
	Post-Dose ⬤

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

US3272031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

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

Date of examination *(dd MMM yyyy)*   01 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	PATIENT HAS BREAST CANCER AND WILL BE UNDERGOING RADIATION
What was the study treatment?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ◯
	Right Arm ◯
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	01 SEP 2020
Collection time *(00:00-23:59)*	12:35 (24 HR)
Collection date and time (derived)	01 SEP 2020 12:35

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*			01 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:29	01 SEP 2020 12:29
Nasopharyngeal Swab 2	No		

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

US3272031

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: ▓▓▓ (b) (4) ▓▓▓ **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                      No ◯

Continuing Flag   1

US3272031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3272031

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3272031

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: ☐☐☐ (b) (4) ☐☐☐ **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                                       No ◯

Continuing Flag   1

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT3

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: [REDACTED] (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	11:56 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:56
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4)   **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was the physical examination performed?   Yes ●

                                                           No ◯

Date of examination *(dd MMM yyyy)*   29 SEP 2020

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

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	12:06 (24 HR)
Collection date and time (derived)	29 SEP 2020 12:06

US3272031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 16:58:06**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	05 OCT 2020 09:21:28
Patient Cloud Open Date & Time	01 OCT 2020 00:01
Patient Cloud Close Date & Time	05 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 10:44:23
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	15 OCT 2020 07:33:20
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 07:14:17
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 10:16:16
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 NOV 2020 07:37:22
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 113

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-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 ⃝

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 07:17:10
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	23 NOV 2020 07:38:59
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	30 NOV 2020 07:28:33
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	14 DEC 2020 07:25:17
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	21 DEC 2020 07:26:12
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	28 DEC 2020 07:12:23
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	04 JAN 2021 14:46:23
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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	11 JAN 2021 07:22:46
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 09:14:21
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

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

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments _____

US3272031

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3272031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3272031

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3272031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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   _____

US3272031

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?   Yes ◯

                                                                    No ●

Continuing Flag

US3272031
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 16:22:39

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact

Clinic Visit - Scheduled ◯
Clinical Visit - Unscheduled ◯
Safety Call ◯
Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ◯
No ◯

| Generate Next COVID-19 Assessment | Yes 〇 |
| | No 〇 |

US3272031

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

Form: Visit Date

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	20 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3272031

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

Form: Unblinding

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Date of updated informed consent *(dd MMM yyyy)*	20 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)*	20 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	

Data signed: [b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00-23:59)*	11:12 (24 HR)
Collection date and time (derived)	20 JAN 2021 11:12

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	20 JAN 2021
Collection time *(00:00 - 23:59)*	11:21
Collection Date and Time (derived)	20 JAN 2021 11:21

US3272031

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Did the participant experience any adverse events? Yes ●

No ○

If Yes, enter details on the Adverse Events form.

AEID	USA-US070-2020-MRNA-1273-P30 1000001
Adverse event	STAGE 1 LEFT BREAST CANCER

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)*	17 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	27 AUG 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU? Yes ○ No ○ Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True

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 DIAGNOSED WITH STAGE 1 BREAST CANCER. SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. BIOPSY PREFORMED ON 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020. PATHOLOGY OF BOTH MASSES REVELED INVASIVE DUCTAL CARCINOMA, GRADE 2, ER/PR 100% POSITIVE, HER-2 NEGATIVE, PERINEURAL INVASION PRESENT AND DCIS.
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)	

FDA-CBER-2022-1614-1612327

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

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

                                                                           No ◯

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

Name of Medication	LEVOTHYROXINE

Prophylaxis

Yes ○
No ●

Indication	GRAVES DISEASE
Dose per administration	175

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

FDA-CBER-2022-1614-1612329

	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 2006
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: [(b) (4)] **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE

Prophylaxis	Yes	○
	No	●

Indication	HYPERTENSION
Dose per administration	12.5/100

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	○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

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 2015
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-1612332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4)   **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	METFORMIN ER

Prophylaxis   Yes ○

No ⬤

Indication	TYPE 2 DIABETES
Dose per administration	500

Dose unit   mg ⬤

ug ○

mL ○

g ○

IU ○

tablet ○

capsule ○

puff ○

Other ○

If dose unit is Other, specify   _____

Frequency   once daily ⬤

twice daily ○

three times daily ○

four times daily ○

every other day ○

every week ○

every month ○

as needed ○

once ○

unknown ○

other ○

If frequency is Other, specify   _____

Route of administration   Oral ⬤

Topical ○

Subcutaneous ○

Transdermal ○

Intraocular ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

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 ⬤

Name of Medication	BENADRYL

Prophylaxis	Yes ⚪
	No ⬤

Indication	SEASONAL ALLERGIES

Dose per administration	25

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

FDA-CBER-2022-1614-1612335

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)	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 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ⬤
	No ◯
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration
- Oral ⬤
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2013
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: ▓▓▓ (b) (4) ▓▓▓ **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	L-LYSINE
Prophylaxis	Yes ⬭
	No ⬤
Indication	HERPES SIMPLEX 1
Dose per administration	500
Dose unit	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ⬭
	three times daily ⬭
	four times daily ⬭
	every other day ⬭
	every week ⬭
	every month ⬭
	as needed ⬭
	once ⬭
	unknown ⬭
	other ⬭
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭
	Intraocular ⬭

PRODUCTION RELEASE (v12.003
EAB) (1725)

	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 1975
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯

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

Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	OMEPRAZOLE

Prophylaxis
Yes ◯
No ⬤

Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration
Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

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 2015
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

FDA-CBER-2022-1614-1612342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: [(b) (4)] **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	VITAMIN D3
Prophylaxis	Yes ●
	No ○
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	50
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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	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 (9)

Data signed: [(b) (4)] **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	VITAMIN B
Prophylaxis	Yes ●
	No ○
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	250
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

FDA-CBER-2022-1614-1612345

	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)*	15 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

FDA-CBER-2022-1614-1612346

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	SYMBICORT
Prophylaxis	Yes ⭕
	No ⬤
Indication	EMPHYSEMA
Dose per administration	160/4.5
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)*	15 MAY 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	CLOBETASOL PROPIONATE
Prophylaxis	Yes ⭕
	No ⬤
Indication	LICHEN SCLEROSES
Dose per administration	NA
Dose unit	mg ⭕
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⬤
If dose unit is Other, specify	NA
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	TWICE A WEEK
Route of administration	Oral ⭕
	Topical ⬤
	Subcutaneous ⭕
	Transdermal ⭕
	Intraocular ⭕

PRODUCTION RELEASE (v12.003
EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	BLACK COHOSH
Prophylaxis	Yes ●
	No ◯
Indication	VASOMOTOR SYMPTOMS
Dose per administration	540
Dose unit	mg ●
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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 (13)

Data signed: [(b) (4)] **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

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 ○

FDA-CBER-2022-1614-1612353

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)*	22 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	22 SEP 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: ▮▮▮ (b) (4) ▮▮▮ **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	CLOBETASOL PROPIONATE
Prophylaxis	Yes ◯
	No ⬤
Indication	LICHEN SCLEROSUS
Dose per administration	1
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	APPLICATION
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	TWICE WEEKLY
Route of administration	Oral ◯
	Topical ⬤
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4)   **29 Apr 2021 16:57:34**

Generated On: 09 Jun 2021 16:22:39

Name of Medication	LETROZOLE
Prophylaxis	Yes ◯
	No ⬤
Indication	STAGE 1 BREAST CANCER
Dose per administration	2.5
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 ◯

FDA-CBER-2022-1614-1612357

	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 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4)   **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
26 AUG 2020	LUMPECTOMY	Adverse Event	
5 AUG 2020	BIOPSY ON LEFT BREAST	Diagnostic	

US3272031

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

Date of dosing discontinuation (dd MMM yyyy)	1 SEP 2020
Primary reason for dosing discontinuation	AE (specify) ○
	SAE (specify) ○
	Death ○
	Lost To Follow-up ○
	Physician decision (specify) ○
	Pregnancy ○
	Protocol deviation (specify) ○
	Study Terminated By Sponsor ○
	Withdrawal of consent by participant (specify) ○
	Due to SARS-COV-2 ○
	Other ●
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT UNDERGOING CANCER TREATMENT. SUBJECT STILL IN STUDY FOR SAFETY FOLLOWUP

Date of study discontinuation/completion *(dd MMM yyyy)*	20 JAN 2021

Reason for discontinuation	
	AE (specify) ◯
	SAE (specify) ◯
	Complete ◯
	Death ◯
	Lost To Follow-up ◯
	Physician decision (specify) ◯
	Pregnancy ◯
	Protocol deviation (specify) ◯
	Study Terminated By Sponsor ◯
	Withdrawal of consent by participant (specify) ●
	Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT NO LONGER WISHES TO BE IN STUDY CAME IN FOR UNBLINDING APPOINTMENT AND SIGNED NEW CONSENT THAT SHE NO LONGER WISHED TO CONTINUE IN STUDY AND WAS UNBLINDED AS WELL.

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 ◯

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

SAEID	USA-US070-2020-MRNA-1273-P30 1000001
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

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: ████ (b) (4) ████ **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

SAEID	USA-US070-2020-MRNA-1273-P30 1000001
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/AUG/2020 13:16
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

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

SAEID	USA-US070-2020-MRNA-1273-P30 1000001
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)	27/AUG/2020 12:20
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

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: [(b) (4)] **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

SAEID	USA-US070-2020-MRNA-1273-P30 1000001
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)	09/SEP/2020 21:14
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.	True

FDA-CBER-2022-1614-1612366

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: [redacted] (b) (4) **29 Apr 2021 16:57:35**

Generated On: 09 Jun 2021 16:22:39

SAEID	USA-US070-2020-MRNA-1273-P30 1000001
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)	15/SEP/2020 09:30
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

US3272031 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272031

Form: Participant Creation

Generated On: 09 Jun 2021 16:22:39

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:56:15
User entered 'US3272031'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:13

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05

US3272031
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:14:54

US3272031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:14

US3272031
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:38
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:14:54

US3272031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'SCRN'	System	01 Aug 2020 19:14:54

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:22:39
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:15

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '67'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:22:39
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'YEARS'	System	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '67'	System	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:22:55
Query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:19:52
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:19:46
User entered 'Female (F)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:19:46
User opened query 'PV Query: Please confirm the patients sex as male (given MH of postmenopausal, total hysterectomy, etc).' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:26:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered 'Male (M)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:22:39

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:22:39
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:22:39
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:22:39

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:45
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:27

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Aug 2020'	System	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2020'	System	01 Aug 2020 19:15:40

US3272031
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:22:39
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Amendment 1 (1)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:40

US3272031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:22:39

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:39:14

US3272031
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:22:39
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '1'	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:22:39

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:08:56
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:22:39

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:08
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:13

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:09
Data point term sent to Coder	System	01 Aug 2020 20:20:15
User entered 'Total right knee replacement'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:19:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Aug 2019'	System	01 Aug 2020 20:19:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2019'	System	01 Aug 2020 20:19:52

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US3272031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Aug 2019'	System	01 Aug 2020 20:19:52

FDA-CBER-2022-1614-1612410

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2019'	System	01 Aug 2020 20:19:52

FDA-CBER-2022-1614-1612411

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 18:10:08
Data point term sent to Coder	System	01 Aug 2020 20:21:15
User entered 'total left knee replacement'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un Oct 2016'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un Oct 2016'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Oct 2016'	System	01 Aug 2020 20:21:07

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Oct 2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2016'	System	01 Aug 2020 20:21:07

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:23:10
Data point term sent to Coder	System	01 Aug 2020 20:22:16
User entered 'Cholecystectomy'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

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US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:21:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:21:43

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:21:43

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:23:10
Data point term sent to Coder	System	01 Aug 2020 20:22:16
User entered 'Cholecystitis'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

FDA-CBER-2022-1614-1612436

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:22:04

US3272031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:22:04

Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:22:04

FDA-CBER-2022-1614-1612441

US3272031
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:22:39
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:24:10
Data point term sent to Coder	System	01 Aug 2020 20:23:17
User entered 'Total Hysterectomy'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2002'	System	01 Aug 2020 20:22:32

US3272031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2002'	System	01 Aug 2020 20:22:32

US3272031
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:22:39
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
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)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:24:10
Data point term sent to Coder	System	01 Aug 2020 20:23:16
User entered 'Menorrhagia'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'UN UNK 2002' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:02:55
User entered 'UN Apr 2002' reason for change: Data Entry Error		17 Nov 2020 17:02:33
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	17 Nov 2020 17:02:55
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	17 Nov 2020 17:02:33
User entered 'un UNK 2002'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

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US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2002'	System	17 Nov 2020 17:02:55
User entered 'Apr 2002'	System	17 Nov 2020 17:02:33
User entered 'Jan 2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2002'	System	01 Aug 2020 20:22:51

US3272031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2002'	System	01 Aug 2020 20:22:51

US3272031
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:22:39
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:01:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Papulosquamous conditions, PT: Lichen sclerosus, LLT: Lichen sclerosus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 07:28:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 07:28:17
Data point term sent to Coder	System	01 Oct 2020 21:25:36
Query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:24:54
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:24:49
User entered 'LICHEN SCLEROSUS Bilateral Lower extremities' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:24:49
User opened query 'Per DM CLR: Please specify the location of LICHEN SCLEROSUS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:56:50
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Papulosquamous conditions, PT: Lichen sclerosus, LLT: Lichen sclerosus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:24:10

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Aug 2020 20:23:16
User entered 'Lichen Sclerosus'	Kayla Flege (b) (4)	01 Aug 2020 20:23:14
	(b) (4)	

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

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US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2018'	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2018'	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:23:14

US3272031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:23:14

US3272031
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:22:39
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Herpes simplex oral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:27:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:27:52
User closed query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:03:24
Data point term sent to Coder	System	01 Oct 2020 21:25:36
Query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:23
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:09
User entered 'Oral HERPES SIMPLEX 1' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:25:09
User opened query 'Per DM CLR: Please specify the location of HERPES SIMPLEX 1. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:57:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:51:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:51:08
Data point term sent to Coder	System	01 Aug 2020 20:25:17
User entered 'Herpes Simplex 1'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 1975'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

FDA-CBER-2022-1614-1612474

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 1975'	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '1975'	System	01 Aug 2020 20:24:36

US3272031
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:22:39
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:24:36

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
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)	01 Aug 2020 20:26:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:26:10
Data point term sent to Coder	System	01 Aug 2020 20:25:17
User entered 'Gastroesophageal Reflux Disease'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

FDA-CBER-2022-1614-1612487

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:24:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:24:59

FDA-CBER-2022-1614-1612490

US3272031
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:24:59

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:05:01
Query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Emphysema is located in lungs' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:22:38
User opened query 'Per DM CLR: Please specify the location and/or type of EMPHYSEMA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:57:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:27:11
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Emphysema'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '15 May 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

US3272031
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:22:39
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'May 2020'	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2020'	System	01 Aug 2020 20:25:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:25:23

FDA-CBER-2022-1614-1612501

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:25:23

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:35:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 09:35:59
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Graves Disease'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2006'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

FDA-CBER-2022-1614-1612507

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2006'	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2006'	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:25:47

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:07:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:28:47
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:58:02
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:27:11
Data point term sent to Coder	System	01 Aug 2020 20:26:18
User entered 'Hypertension'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	01 Aug 2020 20:26:12

US3272031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:26:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:26:12

FDA-CBER-2022-1614-1612522

US3272031
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 16:22:39
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:11
Data point term sent to Coder	System	01 Aug 2020 20:27:19
User entered 'Seasonal Allergies'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2000'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

FDA-CBER-2022-1614-1612527

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2000'	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2000'	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:26:52

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:28:12
Data point term sent to Coder	System	01 Aug 2020 20:27:20
User entered 'Bilateral Knee Pain'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2014'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '06 Aug 2019'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2014'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2014'	System	01 Aug 2020 20:27:15

FDA-CBER-2022-1614-1612540

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Aug 2019'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2019'	System	01 Aug 2020 20:27:15

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:09:11
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:05
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:58:31
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)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:20
User entered 'Type 2 Diabetes'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2018'	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2018'	System	01 Aug 2020 20:27:39

US3272031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:27:39

FDA-CBER-2022-1614-1612551

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:27:39

FDA-CBER-2022-1614-1612552

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:44:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:44:39
Data point term sent to Coder	System	06 Sep 2020 18:43:03
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User entered 'Severe OBESITY' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:21
User entered 'Obesity'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:04:35
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' (Site from DM).		09 Sep 2020 13:26:08
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:30
User entered 'un UNK 2010' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:42:25
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:05:03
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2015'	System	17 Nov 2020 17:04:35
User entered 'Jan 2010'	System	06 Sep 2020 18:42:25
User entered 'Aug 2020'	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2015'	System	17 Nov 2020 17:04:35
User entered '2010'	System	06 Sep 2020 18:42:25
User entered '2020'	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:28:00

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
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)	01 Aug 2020 20:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:29:12
Data point term sent to Coder	System	01 Aug 2020 20:28:21
User entered 'Postmenopausal'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:10:23
Query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:30
User entered 'UN UNK 2002' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:26
User opened query 'Per DM CLR: Please note, Start date of MH = UN UNK 2020. However, Post-menopausal date recorded in Childbearing eCRF is UN UNK 2002. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:59:20
User entered 'un UNK 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jan 2002'	System	01 Oct 2020 21:29:26
User entered 'Jan 2020'	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2002'	System	01 Oct 2020 21:29:26
User entered '2020'	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:28:19

US3272031
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered empty.	System	01 Aug 2020 20:28:19

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast imaging procedures, PT: Mammogram, LLT: Mammogram - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:19:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:19:46
Data point term sent to Coder	System	13 Nov 2020 18:18:59
User entered 'Mammogram'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 16:22:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '28 Jul 2020'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 18:18:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 18:18:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 18:18:55
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 18:18:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '28 Jul 2020'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

US3272031
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 16:22:39
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:18:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jul 2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'Jul 2020'	System	13 Nov 2020 18:18:48

US3272031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:22:39

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '2020'	System	13 Nov 2020 18:18:48

US3272031
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:51
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:21:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:14:28
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)	29 Sep 2020 10:14:28
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 'vitals in visit 1 day 1 as screening was done same day' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:43:11
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).	(b) (4), (b) (6)	24 Sep 2020 18:55:33
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:53
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:02
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:10
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:55
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:06
User entered '12:46' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:24
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '12:46'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '01 Aug 2020 12:46'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered '01 Aug 2020 12:46'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:56
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:10
User entered '175.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '175.0' cm	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:47:58
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:13
User entered '123.0' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:15:53
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '123.0' kg	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered '40.16327'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered '40.2'	System	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'kg/m2'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'kg/m2'	System	01 Aug 2020 20:29:34
DataPoint set to visible.	System	01 Aug 2020 19:15:43

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:48:01
Query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:22:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
User opened query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:16:17
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).	(b) (4), (b) (6)	29 Sep 2020 10:16:17
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).	(b) (4), (b) (6)	15 Sep 2020 23:27:36
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
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).	(b) (4), (b) (6)	15 Sep 2020 20:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:27:31
DataPoint Verified.		21 Aug 2020 17:09:28
User entered 'Tympanic'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '80'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'bpm'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'bpm'	System	01 Aug 2020 20:29:34

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:28
User entered '20'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'breaths/min'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'breaths/min'	System	01 Aug 2020 20:29:34

US3272031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:27:31
DataPoint Verified.		21 Aug 2020 17:09:28
User entered '125'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'mmHg'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'mmHg'	System	01 Aug 2020 20:29:34

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:18:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:27:31
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:27:31
DataPoint Verified.		21 Aug 2020 17:09:28
User entered '73'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:34

US3272031
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User entered 'mmHg'	System	30 Sep 2020 18:18:46
User entered empty.	System	15 Sep 2020 23:27:31
User entered 'mmHg'	System	01 Aug 2020 20:29:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15

US3272031

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:39

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:46

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:39

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:04:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:21:08
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:36
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:29:46

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '1 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

US3272031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'UN UNK 2002'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 20:31:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 20:31:19
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:19
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 20:30:40
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:22:39
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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:22:39
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:22:39
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered 'Biking, grocery shopping, socialization with friends.'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

FDA-CBER-2022-1614-1612628

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 20:30:40
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:22:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:22:39
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:09:42
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:30:40

US3272031
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

US3272031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:16
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:32

US3272031
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'VISIT1'	System	01 Aug 2020 20:31:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

US3272031
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:22:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:38:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:38:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 18:44:09
User entered '184340' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:39

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:44:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:22:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:30
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:31:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).		09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:22:39
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:22:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '12:46'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '01 Aug 2020 12:46'	System	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:01:28
User entered 'Tympanic'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '80'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:22:39
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'bpm'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '20'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'breaths/min'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '125'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '73'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'mmHg'	System	01 Aug 2020 20:33:38

US3272031
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:22:39
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:23:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:02:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:49:58
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:36
User entered '175.0' cm	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:22:39
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:02:50
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:50:08
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:47:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:47:37
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:34:47
User entered '123.0' kg	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:18:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:34:02
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	01 Aug 2020 20:33:38
User entered '14:39'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '01 Aug 2020 14:39'	System	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '36.6' C	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

US3272031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Other (Other)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:01:28
User entered 'Tympanic'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '78'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'bpm'	System	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '18'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'breaths/min'	System	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '127'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'mmHg'	System	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '78'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:33:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'mmHg'	System	01 Aug 2020 20:33:38

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:48
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:36:28

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:39

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:48
User entered '01 Aug 2020'	Kayla Flege (b) (4)	01 Aug 2020 20:36:28

US3272031
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:22:39
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 20:36:47
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	01 Aug 2020 20:36:47
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 19:16:06
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1
Form: Exposure
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If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1

Form: Exposure

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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)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:22:39
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 19:16:06

Folder: Visit 1 Day 1
Form: Exposure
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What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered '14:09'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '01 Aug 2020 14:09'	System	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:22:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:36:47
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:45
User entered 'ONCE'	System	01 Aug 2020 19:16:06

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 19:16:06

FDA-CBER-2022-1614-1612698

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

US3272031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:53
User entered '13:26'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '01 Aug 2020 13:26'	System	01 Aug 2020 20:37:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:39

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

FDA-CBER-2022-1614-1612705

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '13:11'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '01 Aug 2020 13:11'	System	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered empty.	System	01 Aug 2020 20:37:21

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Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:21:58
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 20:38:34

US3272031
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:18:04
User entered '1'	System	01 Aug 2020 20:38:34

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:51:45', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered 'Yes (Y)'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:51:55', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered '97.8'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:03', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered 'No (N)'	System	01 Aug 2020 19:52:24

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '77c4796c-dd42-49d7-8cf0-47c66b7eb7ee'	System	01 Aug 2020 19:52:24
User entered '01 Aug 2020 14:52'	System	01 Aug 2020 19:52:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

FDA-CBER-2022-1614-1612719

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T17:59:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered 'Yes (Y)'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:01:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered '97.4'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:01:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered 'No (N)'	System	01 Aug 2020 23:02:04

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '565e3e07-20a7-4c96-911a-803be959e428'	System	01 Aug 2020 23:02:04
User entered '01 Aug 2020 18:02'	System	01 Aug 2020 23:02:04

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered 'Yes (Y)'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered '96.0'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered 'No (N)'	System	02 Aug 2020 21:04:59

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:04:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6f833856-054e-4107-9957-fb21220ce6bf'	System	02 Aug 2020 21:04:59
User entered '02 Aug 2020 16:04'	System	02 Aug 2020 21:04:59

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:27', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered 'Yes (Y)'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered '98.6'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered 'No (N)'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:01:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '482aeac0-39e6-4f0a-9b98-8025f15c501d'	System	03 Aug 2020 20:01:57
User entered '03 Aug 2020 15:01'	System	03 Aug 2020 20:01:57

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered 'Yes (Y)'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:48', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered '97.9'	System	04 Aug 2020 20:30:05

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US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:29:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered 'No (N)'	System	04 Aug 2020 20:30:05

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '62a5734f-3211-4a7d-ba1b-b230b1b36e2b'	System	04 Aug 2020 20:30:05
User entered '04 Aug 2020 15:30'	System	04 Aug 2020 20:30:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:36', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered 'Yes (Y)'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:45', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered '96.9'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:51', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered 'No (N)'	System	05 Aug 2020 19:47:05

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US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:46:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'bcfa2ecb-4d90-4ae7-a7e6-e2cb14552dbf'	System	05 Aug 2020 19:47:05
User entered '05 Aug 2020 14:46'	System	05 Aug 2020 19:47:05

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:52:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered 'Yes (Y)'	System	06 Aug 2020 18:53:13

FDA-CBER-2022-1614-1612757

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:52:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered '96.3'	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered 'No (N)'	System	06 Aug 2020 18:53:13

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '940b54f0-20e2-4ca3-893a-bb73f44f320f'	System	06 Aug 2020 18:53:13
User entered '06 Aug 2020 13:53'	System	06 Aug 2020 18:53:13

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

FDA-CBER-2022-1614-1612761

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:22:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:16:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered 'Yes (Y)'	System	07 Aug 2020 19:17:16

FDA-CBER-2022-1614-1612764

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:22:39

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:16:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered '97.9'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered 'No (N)'	System	07 Aug 2020 19:17:16

US3272031
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'ac3583a5-f008-479e-b6c3-8eeb1230c166'	System	07 Aug 2020 19:17:16
User entered '07 Aug 2020 14:17'	System	07 Aug 2020 19:17:16

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:52:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'None (1)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'No (N)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:09', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'No (N)'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered 'None (1)'	System	01 Aug 2020 19:53:35

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '280536ef-8564-4d7d-9a4a-fa575b7be4f8'	System	01 Aug 2020 19:53:35
User entered '01 Aug 2020 14:53'	System	01 Aug 2020 19:53:35

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'None (1)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'No (N)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:21', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'No (N)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered 'None (1)'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:44', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c57fe528-08ca-4c5d-816d-6458c1f49fa9'	System	01 Aug 2020 23:02:50
User entered '01 Aug 2020 18:02'	System	01 Aug 2020 23:02:50

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'None (1)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'No (N)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'No (N)'	System	02 Aug 2020 21:05:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:24', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered 'None (1)'	System	02 Aug 2020 21:05:42

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:37', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '30b1958d-fac1-4f25-8edc-6e2204ef31e5'	System	02 Aug 2020 21:05:42
User entered '02 Aug 2020 16:05'	System	02 Aug 2020 21:05:42

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:22:39
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'None (1)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'No (N)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:14', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'No (N)'	System	03 Aug 2020 20:02:36

FDA-CBER-2022-1614-1612797

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered 'None (1)'	System	03 Aug 2020 20:02:36

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:31', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'af478b55-3b85-4bf7-9d0d-79007271d8ed'	System	03 Aug 2020 20:02:36
User entered '03 Aug 2020 15:02'	System	03 Aug 2020 20:02:36

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:22:39
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:08', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'None (1)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'No (N)'	System	04 Aug 2020 20:30:33

FDA-CBER-2022-1614-1612804

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'No (N)'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered 'None (1)'	System	04 Aug 2020 20:30:33

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a7762560-cbd0-4a6b-82ce-a6c6238adacf'	System	04 Aug 2020 20:30:33
User entered '04 Aug 2020 15:30'	System	04 Aug 2020 20:30:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:22:39
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:09', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'None (1)'	System	05 Aug 2020 19:47:33

FDA-CBER-2022-1614-1612811

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'No (N)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'No (N)'	System	05 Aug 2020 19:47:33

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered 'None (1)'	System	05 Aug 2020 19:47:33

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:22:39
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '99c5a55d-aff5-4859-af39-a650a354261d'	System	05 Aug 2020 19:47:33
User entered '05 Aug 2020 14:47'	System	05 Aug 2020 19:47:33

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

FDA-CBER-2022-1614-1612816

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:14', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'None (1)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:18', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'No (N)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'No (N)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:27', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered 'None (1)'	System	06 Aug 2020 18:53:42

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:31', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'c6c70121-8b9f-4453-90f7-1501fb748052'	System	06 Aug 2020 18:53:42
User entered '06 Aug 2020 13:53'	System	06 Aug 2020 18:53:42

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

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US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'None (1)'	System	07 Aug 2020 19:18:03

FDA-CBER-2022-1614-1612827

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:24', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'No (N)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:32', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'No (N)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered 'None (1)'	System	07 Aug 2020 19:18:03

US3272031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:22:39

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'eae2ba64-d7b8-4b6f-b175-e8f67619dbed'	System	07 Aug 2020 19:18:03
User entered '07 Aug 2020 14:17'	System	07 Aug 2020 19:18:03

US3272031
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:51', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:54', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:53:57', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'None (0)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:54:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered 'No (N)'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T14:54:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b697df38-3ca4-42b3-ba7c-4b0d15797af4'	System	01 Aug 2020 19:54:23
User entered '01 Aug 2020 14:54'	System	01 Aug 2020 19:54:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 14:29'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 16:59'	System	01 Aug 2020 19:16:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:02:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'None (0)'	System	01 Aug 2020 23:03:34

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered 'No (N)'	System	01 Aug 2020 23:03:34

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-01T18:03:30', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '560a0216-a759-4536-a467-8f36820a559b'	System	01 Aug 2020 23:03:34
User entered '01 Aug 2020 18:03'	System	01 Aug 2020 23:03:34

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '01 Aug 2020 17:54'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 2'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:44', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

FDA-CBER-2022-1614-1612857

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:05:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:22:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'None (0)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered 'No (N)'	System	02 Aug 2020 21:06:23

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-02T16:06:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'da3e349e-09b4-4816-ae61-d769c04fa083'	System	02 Aug 2020 21:06:23
User entered '02 Aug 2020 16:06'	System	02 Aug 2020 21:06:23

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:22:39
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 3'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:50', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:22:39
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:02:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'None (0)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:03:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered 'No (N)'	System	03 Aug 2020 20:03:14

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-03T15:03:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4affca25-73d8-4ec2-9f44-95906adc1718'	System	03 Aug 2020 20:03:14
User entered '03 Aug 2020 15:03'	System	03 Aug 2020 20:03:14

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

FDA-CBER-2022-1614-1612876

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 4'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:22:39
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:35', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:42', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:49', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:30:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'None (0)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:31:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered 'No (N)'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-04T15:31:07', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '606dbbda-d758-4326-ae40-4a1171cc1df7'	System	04 Aug 2020 20:31:13
User entered '04 Aug 2020 15:31'	System	04 Aug 2020 20:31:13

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 5'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:37', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:40', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:50', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:22:39
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'None (0)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:47:58', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered 'No (N)'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-05T14:48:04', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0b605562-a86f-4498-93f2-7e183173e76c'	System	05 Aug 2020 19:48:08
User entered '05 Aug 2020 14:48'	System	05 Aug 2020 19:48:08

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 6'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:38', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:41', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:43', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:22:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:53:55', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'None (0)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:54:03', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered 'No (N)'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-06T13:54:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'f07ef806-893d-4734-997e-9268e15a7400'	System	06 Aug 2020 18:54:25
User entered '06 Aug 2020 13:54'	System	06 Aug 2020 18:54:25

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:22:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 7'	System	01 Aug 2020 19:16:06

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:22:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:53', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:22:39
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:22:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:17:58', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:22:39
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:02', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:22:39
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:05', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:22:39
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'None (0)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:15', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered 'No (N)'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:22:39

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a648011f760a813a)', Time: '2020-08-07T14:18:25', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '10212d32-771c-4d3a-a15b-ad06fac665b3'	System	07 Aug 2020 19:18:30
User entered '07 Aug 2020 14:18'	System	07 Aug 2020 19:18:30

US3272031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:22:39

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 19:16:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered '10 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:11:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:31

US3272031
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:12:10
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:22:49

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:42
User entered '1'	System	14 Aug 2020 00:22:49

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '17 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:19:13

US3272031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:16

US3272031
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:16
User entered '1'	System	02 Sep 2020 20:19:16

US3272031
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 12:26:12
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm correct' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 20:19:32
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Sep 2020 20:19:25
User entered '26 Aug 2020'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:19:25

US3272031
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:20:37

US3272031
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:36:12
User entered '1'	System	02 Sep 2020 20:20:37

US3272031
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

US3272031
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 20:21:08

US3272031
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered 'VISIT2'	System	02 Sep 2020 20:21:08

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User accepted default value 'Pre-Dose (PREDOSE)'		02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:22:39

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '12:10'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered '01 Sep 2020 12:10'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '37.3' C	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '81'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered 'bpm'	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '18'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered 'breaths/min'	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612955

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '119'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered 'mmHg'	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612957

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '73'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered 'mmHg'	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612959

US3272031
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:22:39
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User accepted default value 'Post-Dose (POSTDOSE)'		02 Sep 2020 20:22:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:22:39
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

US3272031
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:22:39
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:22:03

US3272031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612971

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612973

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:22:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:22:03

FDA-CBER-2022-1614-1612975

US3272031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:39

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:22:56

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:22:56

FDA-CBER-2022-1614-1612977

US3272031
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:22:39

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

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)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Patient has breast cancer and will be undergoing radiation'	(b) (4), (b) (6)	02 Sep 2020 20:23:58

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:23:58

FDA-CBER-2022-1614-1612981

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:23:58

US3272031
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:22:39
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:23:58

US3272031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:22:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:23:58

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:22:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:23:58

FDA-CBER-2022-1614-1612987

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '12:35'	(b) (4), (b) (6)	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered '01 Sep 2020 12:35'	System	02 Sep 2020 20:24:21

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '12:29'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered '01 Sep 2020 12:29'	System	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:24:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered empty.	System	02 Sep 2020 20:24:31

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 20:24:43

US3272031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:15
User entered '1'	System	02 Sep 2020 20:24:43

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

FDA-CBER-2022-1614-1613004

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:22:23

US3272031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:22:16

US3272031
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:13
User entered '1'	System	08 Sep 2020 23:22:16

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:33:27

FDA-CBER-2022-1614-1613011

US3272031
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:33:27

US3272031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:30

US3272031
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:57
User entered '1'	System	22 Sep 2020 15:33:30

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:33:37

US3272031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:40

US3272031
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:54
User entered '1'	System	22 Sep 2020 15:33:40

US3272031
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:58:34

US3272031
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'VISIT3'	System	29 Sep 2020 17:58:34

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

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US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '11:56'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '29 Sep 2020 11:56'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '36.9' C	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Oral (Oral)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '73'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'bpm'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '16'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'breaths/min'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '137'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'mmHg'	System	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '74'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:01

US3272031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:22:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'mmHg'	System	29 Sep 2020 17:59:01

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04

US3272031
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:22:39
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04

US3272031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:22:39

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:11

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 16:22:39

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:11

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '29 Sep 2020'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

US3272031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered '12:06'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '29 Sep 2020 12:06'	System	29 Sep 2020 17:59:23

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US3272031
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:58:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	29 Sep 2020 17:59:29

US3272031
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '1'	System	29 Sep 2020 17:59:29

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 64'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered 'No (N)'	System	05 Oct 2020 14:21:30

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered 'No (N)'	System	05 Oct 2020 14:21:30

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-05T09:21:28', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '3378afcc-c432-4070-856b-8fc87dc4de62'	System	05 Oct 2020 14:21:30
User entered '05 Oct 2020 09:21:28'	System	05 Oct 2020 14:21:30

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 71'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered 'No (N)'	System	12 Oct 2020 15:44:25

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:08', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered 'No (N)'	System	12 Oct 2020 15:44:25

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-12T10:44:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '570c1918-ccd5-49b8-a40e-8eaf193e7a40'	System	12 Oct 2020 15:44:25
User entered '12 Oct 2020 10:44:23'	System	12 Oct 2020 15:44:25

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 78'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered 'No (N)'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:15', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered 'No (N)'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-15T07:33:20', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '2e846fcf-b4be-4ff5-abc2-1fc8576a82d3'	System	15 Oct 2020 12:33:20
User entered '15 Oct 2020 07:33:20'	System	15 Oct 2020 12:33:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 92'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-29T07:13:47', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered 'No (N)'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-29T07:13:57', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered 'No (N)'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-10-29T07:14:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '58cd2b3a-be6a-415d-822e-91e191e13cb6'	System	29 Oct 2020 12:14:20
User entered '29 Oct 2020 07:14:17'	System	29 Oct 2020 12:14:20

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 99'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:00', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered 'No (N)'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered 'No (N)'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-05T10:16:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '6b537f5a-e5d0-4779-9247-04ea56b716d1'	System	05 Nov 2020 16:16:19
User entered '05 Nov 2020 10:16:16'	System	05 Nov 2020 16:16:19

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 106'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:06', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered 'No (N)'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you been exposed to someone with 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 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered 'No (N)'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-12T07:37:22', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b8e42ce8-be6e-4825-a294-89df8b794a75'	System	12 Nov 2020 13:37:23
User entered '12 Nov 2020 07:37:22'	System	12 Nov 2020 13:37:23

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:31:20
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01
Data entry locked.	System	01 Aug 2020 19:16:06
User entered 'Day 113'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

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US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '19 Nov 2020 00:01'	System	01 Aug 2020 19:16:06

US3272031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:26:01
Data entry locked.	System	01 Aug 2020 19:16:06
User entered '23 Nov 2020 23:59'	System	01 Aug 2020 19:16:06

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-19T07:16:56', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered 'No (N)'	System	19 Nov 2020 13:17:11

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-19T07:17:05', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered 'No (N)'	System	19 Nov 2020 13:17:11

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-19T07:17:10', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7abbd46a-d3de-4786-840c-1ee628cf91f4'	System	19 Nov 2020 13:17:11
User entered '19 Nov 2020 07:17:10'	System	19 Nov 2020 13:17:11

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:42', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered 'No (N)'	System	23 Nov 2020 13:39:00

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:52', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered 'No (N)'	System	23 Nov 2020 13:39:00

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-23T07:38:59', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a2940f0-d654-43f5-b67e-d437f78d7c10'	System	23 Nov 2020 13:39:00
User entered '23 Nov 2020 07:38:59'	System	23 Nov 2020 13:39:00

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-30T07:28:21', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0acf445a-1228-421b-ab5d-21090118a6e2'	System	30 Nov 2020 13:28:33
User entered 'No (N)'	System	30 Nov 2020 13:28:33

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-30T07:28:29', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0acf445a-1228-421b-ab5d-21090118a6e2'	System	30 Nov 2020 13:28:33
User entered 'No (N)'	System	30 Nov 2020 13:28:33

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-11-30T07:28:33', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '0acf445a-1228-421b-ab5d-21090118a6e2'	System	30 Nov 2020 13:28:33
User entered '30 Nov 2020 07:28:33'	System	30 Nov 2020 13:28:33

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-14T07:25:01', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'e5eee742-b770-4fe4-989a-7673a36682df'	System	14 Dec 2020 13:25:17
User entered 'No (N)'	System	14 Dec 2020 13:25:17

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-14T07:25:11', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'e5eee742-b770-4fe4-989a-7673a36682df'	System	14 Dec 2020 13:25:17
User entered 'No (N)'	System	14 Dec 2020 13:25:17

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-14T07:25:17', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'e5eee742-b770-4fe4-989a-7673a36682df'	System	14 Dec 2020 13:25:17
User entered '14 Dec 2020 07:25:17'	System	14 Dec 2020 13:25:17

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-21T07:25:58', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4561ec6c-e4cc-48ba-a0f2-d910ed5d83c5'	System	21 Dec 2020 13:26:15
User entered 'No (N)'	System	21 Dec 2020 13:26:15
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-21T07:26:08', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4561ec6c-e4cc-48ba-a0f2-d910ed5d83c5'	System	21 Dec 2020 13:26:15
User entered 'No (N)'	System	21 Dec 2020 13:26:15
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-21T07:26:12', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '4561ec6c-e4cc-48ba-a0f2-d910ed5d83c5'	System	21 Dec 2020 13:26:15
User entered '21 Dec 2020 07:26:12'	System	21 Dec 2020 13:26:15
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-28T07:12:11', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7c6894eb-fb9f-4ace-969a-6614495bc8c8'	System	28 Dec 2020 13:12:25
User entered 'No (N)'	System	28 Dec 2020 13:12:25
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-28T07:12:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7c6894eb-fb9f-4ace-969a-6614495bc8c8'	System	28 Dec 2020 13:12:25
User entered 'No (N)'	System	28 Dec 2020 13:12:25
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2020-12-28T07:12:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '7c6894eb-fb9f-4ace-969a-6614495bc8c8'	System	28 Dec 2020 13:12:25
User entered '28 Dec 2020 07:12:23'	System	28 Dec 2020 13:12:25
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-04T14:46:13', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a2e5fdcc-5f81-4c06-83e9-6b25ffb48881'	System	04 Jan 2021 20:46:20
User entered 'No (N)'	System	04 Jan 2021 20:46:20
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-04T14:46:19', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a2e5fdcc-5f81-4c06-83e9-6b25ffb48881'	System	04 Jan 2021 20:46:20
User entered 'No (N)'	System	04 Jan 2021 20:46:20
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-04T14:46:23', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'a2e5fdcc-5f81-4c06-83e9-6b25ffb48881'	System	04 Jan 2021 20:46:20
User entered '04 Jan 2021 14:46:23'	System	04 Jan 2021 20:46:20
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-11T07:22:29', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a45a715-da42-4621-afeb-5c4b95e0c798'	System	11 Jan 2021 13:22:47
User entered 'No (N)'	System	11 Jan 2021 13:22:47
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-11T07:22:39', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a45a715-da42-4621-afeb-5c4b95e0c798'	System	11 Jan 2021 13:22:47
User entered 'No (N)'	System	11 Jan 2021 13:22:47
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

FDA-CBER-2022-1614-1613186

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-11T07:22:46', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: '8a45a715-da42-4621-afeb-5c4b95e0c798'	System	11 Jan 2021 13:22:47
User entered '11 Jan 2021 07:22:46'	System	11 Jan 2021 13:22:47
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

FDA-CBER-2022-1614-1613188

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:26:01

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-18T09:14:16', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b440c815-7e8c-4bf3-a820-8b27c31b7b84'	System	18 Jan 2021 15:14:23
User entered 'No (N)'	System	18 Jan 2021 15:14:23
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

FDA-CBER-2022-1614-1613191

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-18T09:14:18', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b440c815-7e8c-4bf3-a820-8b27c31b7b84'	System	18 Jan 2021 15:14:23
User entered 'No (N)'	System	18 Jan 2021 15:14:23
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:22:39

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ce5dc21d52e5733)', Time: '2021-01-18T09:14:21', User OID: 'PatientReportedOutcome (US3272031)', ODM File OID: 'b440c815-7e8c-4bf3-a820-8b27c31b7b84'	System	18 Jan 2021 15:14:23
User entered '18 Jan 2021 09:14:21'	System	18 Jan 2021 15:14:23
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:26:01

US3272031
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:22:39
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
DataPoint Activated.	System	18 Dec 2020 21:55:43
DataPoint Inactivated.	System	16 Dec 2020 21:03:44
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:26:01
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:26:01

FDA-CBER-2022-1614-1613195

Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 14:58:33

US3272031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 14:58:39

FDA-CBER-2022-1614-1613200

US3272031
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:06
User entered '1'	System	26 Oct 2020 14:58:39

US3272031
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 14:31:10

US3272031
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '27 Nov 2020'	(b) (4), (b) (6)	27 Nov 2020 14:31:10

US3272031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Nov 2020 14:31:10

US3272031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	27 Nov 2020 14:31:10

US3272031
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 14:31:16

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:43
User entered '1'	System	27 Nov 2020 14:31:16

US3272031
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 21:55:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 21:55:46

Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:22:39
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 21:55:46

US3272031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:22:39

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 21:55:46

US3272031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 21:55:54

US3272031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:22:39

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	08 Mar 2021 21:55:54

US3272031

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

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 16:54:49

US3272031
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:54:49

US3272031

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

Form: Visit Date

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 16:54:49

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US3272031
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:22:39
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 16:54:49

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 13:07:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:07:41

US3272031
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:22:39

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query '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 blank field.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 15:56:17
Query '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 blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:08:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 13:07:38
User opened query '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 blank field.' (Site from DM).		22 Apr 2021 06:35:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:07:41

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US3272031
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:22:39

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User entered '1'	System	22 Jan 2021 16:55:13

US3272031

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

Form: Unblinding

Generated On: 09 Jun 2021 16:22:39

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User entered empty.	System	22 Jan 2021 16:55:13

Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 16:55:29

US3272031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:55:29

US3272031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '11:12'	(b) (4), (b) (6)	22 Jan 2021 16:55:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User entered '20 Jan 2021 11:12'	System	22 Jan 2021 16:55:29

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US3272031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:39

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 16:55:42

US3272031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:39

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 16:55:42

US3272031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '11:21'	(b) (4), (b) (6)	22 Jan 2021 16:55:42

US3272031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:22:39

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:06
User entered '20 Jan 2021 11:21'	System	22 Jan 2021 16:55:42

US3272031
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 16:22:39

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:18:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:45:23
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:11:11

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
Reviewed for Safety.		19 Aug 2020 17:15:43
User entered 'USA-US070-2020-mRNA-1273-P301000001'	System	19 Aug 2020 17:15:36
User entered 'New'	(b) (4), (b) (6)	19 Aug 2020 17:15:36

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:51:42
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer stage I, LLT: Breast cancer stage I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:39:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:39:24
Query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:48
Data point term sent to Coder	System	30 Sep 2020 18:40:46
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:44
User entered 'STAGE 1 LEFT BREAST CANCER' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:40:44
User opened query 'Per DM CLR: Please specify the location of STAGE 1 BREAST CANCER (e.g. Left, Right or Bilateral). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 06:03:22
User closed query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:16

US3272031
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer stage I, LLT: Breast cancer stage I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:09:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:09:54
Data point term sent to Coder	System	14 Sep 2020 16:08:28
Query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' answered with 'Updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:08:04
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
Coding entries removed.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
User entered 'Stage 1 BREAST CANCER' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:07:28
User opened query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:54
User closed query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:05
Query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' answered with 'Unknown at this time. Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:38:28
User opened query 'PV Query: Please consider updating event term to final diagnosis, including stage of breast cancer.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:58
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:33:46
Data point term sent to Coder	System	18 Aug 2020 21:48:22

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Adverse event

Audit	User	Time (GMT)
User entered 'Breast Cancer'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 13:21:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 13:21:54
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:21:54
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 13:29:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 13:29:27
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:21:54
Query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' answered with 'Diagnosis wasnt until 17 AUG 2020' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:41:50
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	30 Sep 2020 18:41:37
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	30 Sep 2020 18:41:37
User entered '17 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:41:37
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	30 Sep 2020 18:41:04
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	30 Sep 2020 18:41:04
User entered '28 Jul 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:41:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: On 28 July 2020, a breast lump was detected during a routine mammogram. Please consider updating event start date to 28 JUL 2020. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 11:21:30
User closed query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:32
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59
User entered '14 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59
Query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' answered with 'Date is correct.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:08:43
User opened query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:59:40
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '17 Aug 2020'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 21:48:37
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:48:37
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 21:47:43
User entered '10:30'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	18 Aug 2020 21:48:37
User entered '17 Aug 2020 10:30'	System	18 Aug 2020 21:47:43

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:21:54
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:21:54
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:54:23
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:21:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:22:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Completed' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:22:24
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	27 Aug 2020 13:21:54
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:21:54
User entered '27 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:21:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:27:57
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

US3272031
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '1'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '0'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

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Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered '1'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events
Form: Adverse Events (1)
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Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 16:21:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Recovered.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:48
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:37
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:28:12
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
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 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:19:53
User entered empty.	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

Audit	User (b) (4), (b) (6)	Time (GMT)
Data hard locked.		02 May 2021 13:50:05
User closed query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.' (Site from DM).		23 Nov 2020 14:43:24
Query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.' answered with 'Med history updated to include mammogram. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:17:13
User opened query 'Per CDM: Response noted ' 'Subject had mammogram before study started' however, this surgery/procedure is not recorded on the Med Hist eCRF? Please review and update MH as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:22:03
User closed query 'Per DM CLR: As per SAE narrative, "BIOPSY PREFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:02:18
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:57:44
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Subject had mammogram before study started' (Site from DM).	Kayla Flege (b) (4) (b) (4)	02 Nov 2020 21:58:37

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Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:16:28
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:27:46
User closed query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:21:50
Query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 19:30:08
User entered 'SUBJECT DIAGNOSED WITH STAGE 1 BREAST CANCER. SUBJECT HAD A ROUTINE MAMMOGRAM COMPLETED ON 28 JUL 2020. BIOPSY PREFORMED ON 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020. Pathology of both masses reveled invasive ductal carcinoma, grade 2, ER/PR 100% positive, her-2 negative, perineural invasion present and DCIS.' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 19:29:51
Query 'Per DM CLR: As per SAE narrative, "BIOPSY PREFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:43:03

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: As per SAE narrative, "BIOPSY PREFORMED ON 05 AUG 2020", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 06:04:23
User closed query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:52
User closed query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:29:49
User closed query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).		15 Sep 2020 13:29:46
User closed query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).		15 Sep 2020 13:29:44
Query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' answered with 'Routine Mammography.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:17:20
Query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' answered with 'Yes, she is receiving radiation at this time.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:16:50
Query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' answered with 'menorrhagia-noted in medical hx' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:16:14
Query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' answered with 'updated.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:15:31
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59

US3272031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Narrative

Audit	User	Time (GMT)
User entered 'SUBJECT DIAGNOSED WITH Stage 1 BREAST CANCER. Subject had a routine mammogram completed on 28 JUL 2020. Biopsy preformed on 05 AUG 2020. SUBJECT SCHEDULED TO HAVE A LUMPECTOMY ON 26 AUG 2020.' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	14 Sep 2020 16:14:59
User opened query 'PV Query: How was breast cancer detected (i.e routine mammography, breast self-exam, etc)?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:00:20
User opened query 'PV Query: Please confirm if patient will receive any additional treatment, besides lumpectomy (i.e. radiation, chemotherapy)? ' (Site from Safety).		14 Sep 2020 16:00:14
User opened query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).		14 Sep 2020 15:59:14
User opened query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:36
User opened query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:58:29
User closed query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:19:09
User closed query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:19:04

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US3272031
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:46
User closed query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).		10 Sep 2020 01:15:43
User closed query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).		10 Sep 2020 01:15:32
User closed query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' (Site from Safety).		10 Sep 2020 01:15:29
User closed query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:25
User closed query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:15:23
User closed query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).		10 Sep 2020 01:15:18
Query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' answered with 'ok' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:41:41
Query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' answered with 'No.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:41:38
Query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' answered with 'Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:41:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' answered with 'Yes.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:41:05
Query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' answered with 'Will send once reports are back.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:57
Query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' answered with 'Yes it was.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:39:31
Query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' answered with 'Waiting on medical records.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:39:18
User opened query 'PV Query: Did the subject have any risk factors for the breast cancer (i.e. nulliparity or low parity, genetic markers (BRCA1 or BRCA 2), family Hx of cancer, estrogen use, etc)?' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:42:42
User opened query 'PV Query: On 17 Aug 2020, the subject was diagnosed with breast cancer. Please clarify if biopsy results were received on this day.' (Site from Safety).		03 Sep 2020 11:42:31
User opened query 'PV Query: Please provide indication for total hysterectomy (menorrhagia or other?)' (Site from Safety).		03 Sep 2020 11:42:23
User opened query 'PV Query: Please confirm if patient will see an oncologist for the event and if additional treatment will be required (chemo, radiation, etc).' (Site from Safety).		03 Sep 2020 11:42:14
User opened query 'PV Query: Please provide the pathology from the lumpectomy. If results will not fit in narrative, please send with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm that the lumpectomy was performed on 26 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:41:29
User opened query 'PV Query: Please provide date and results of any diagnostic tests performed (i.e. mammogram, ultrasound, CT. etc).' (Site from Safety).		03 Sep 2020 11:41:17
User closed query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosi and assessment by oncologist.' (Site from Safety).		27 Aug 2020 16:22:39
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		27 Aug 2020 16:22:21
User closed query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' (Site from Safety).		27 Aug 2020 16:22:10
Query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosis and assessment by oncologist.' answered with 'NA' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:28
Query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' answered with 'This was found during routine screening prior to randomization day' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:24:09
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'No medications taken' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:41

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US3272031
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:22:39
Narrative

Audit	User	Time (GMT)
Query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Lumpectomy 26 AUG 2020' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:26
Query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'In patient chart' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:23:11
User opened query 'PV Query: Has the patient been seen by an oncologist? If so, please provide diagnosis and assessment by oncologist.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:29:16
User opened query 'PV Query: Please provide initial signs and symptoms. Did the patient discovery abnormality or was this found during routine screening?' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:29:06
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 13:27:20
DataPoint Verified. User opened query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 17:19:53 21 Aug 2020 02:17:33
User opened query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 02:17:15
User entered 'Subject diagnosed with breast cancer. Subject scheduled to have a lumpectomy on 26 AUG 2020.'	Kayla Flege (b) (4) (b) (4)	18 Aug 2020 21:47:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: User entered '1'	System	21 Aug 2020 01:38:45
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:22:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: User entered '1'	System	21 Aug 2020 01:38:45
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:38:42

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:29:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
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)	01 Oct 2020 21:33:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:33:01
Data point term sent to Coder	System	01 Oct 2020 21:31:44
User entered 'Levothyroxine'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Graves Disease'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '175'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

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US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'ug (ug)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2006'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:31:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:31:07

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:33:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:33:48
Data point term sent to Coder	System	01 Oct 2020 21:32:49
User entered 'Losartan potassium/hydrochlorothiazide'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Hypertension'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please review the dose of one component, 125 MG as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 00:41:17
Query 'Per DM CLR: Please review the dose of one component, 125 MG as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:52:16
User entered '12.5/100' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:52:10
User opened query 'Per DM CLR: Please review the dose of one component, 125 MG as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:10:53
User entered '125/100'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:32:09

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
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 HYDROCHLORIDE, PRODUCTSYNONYM: METFORMIN ER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:34:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:34:50
Data point term sent to Coder	System	01 Oct 2020 21:33:53
User entered 'Metformin ER'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Type 2 Diabetes'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '500'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

FDA-CBER-2022-1614-1613331

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:33:06

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:13
Data point term sent to Coder	System	01 Oct 2020 21:35:57
User entered 'Benadryl'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Seasonal Allergies'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '25'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2000'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:35:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:35:16

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:37:52
Data point term sent to Coder	System	01 Oct 2020 21:37:00
User entered 'Multivitamin'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:24:34
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:52:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:52:33
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:47:16
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'tablet (TABLET)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

FDA-CBER-2022-1614-1613361

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:13:32
User entered 'un UNK 2000'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:36:49

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 08:11:46
Data point term sent to Coder	System	01 Oct 2020 21:39:04
User entered 'L-lysine'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Herpes Simplex 1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '500'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 1975'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:38:18

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:38:18

FDA-CBER-2022-1614-1613391

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:38:18

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:39:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:39:54
Data point term sent to Coder	System	01 Oct 2020 21:39:04
User entered 'Omeprazole'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Gastroesophageal Reflux Disease'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2015'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:39:04

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:41:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:41:56
Data point term sent to Coder	System	01 Oct 2020 21:41:06
User entered 'Vitamin D3'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

FDA-CBER-2022-1614-1613411

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:24:43
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'ok ' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:52:53
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:47:50
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '50'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:14:38
User entered 'ug (ug)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:14:38
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

FDA-CBER-2022-1614-1613416

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '15 Jul 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:36
User entered '15 Jun 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

FDA-CBER-2022-1614-1613421

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:40:23

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:42:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:42:57
Data point term sent to Coder	System	01 Oct 2020 21:42:07
User entered 'Vitamin B'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:24:48
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'ok' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:16
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:48:26
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Nutritional Supplement'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '250'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

FDA-CBER-2022-1614-1613436

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '15 Jul 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:41:28

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:43:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:43:59
Data point term sent to Coder	System	01 Oct 2020 21:43:08
User entered 'Symbicort'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Emphysema'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs (e.g. 160mcg/4.5mcg). Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 00:53:17
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs (e.g. 160mcg/4.5mcg). Please verify the dose and unit, and update as appropriate. ' answered with 'ok' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:54:17
User entered '160/4.5' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:56
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs (e.g. 160mcg/4.5mcg). Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 06:49:57
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:56
User entered 'puff (PUFF)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

FDA-CBER-2022-1614-1613451

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mcg' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:53:56
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'twice daily (BID)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '15 May 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '2'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:42:25

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:49:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 04:49:40
Data point term sent to Coder	System	01 Oct 2020 21:44:11
User entered 'Clobetasol Propionate'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Lichen Scleroses'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'NA'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:43:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 21:43:54
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:54
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 21:43:46
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 21:43:59
User entered 'NA' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:59
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Oct 2020 21:43:54
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'other (OTHER)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'twice a week'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Topical (TOPICAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	01 Oct 2020 21:43:46

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CIMICIFUGA RACEMOSA, PRODUCTSYNONYM: BLACK COHOSH [CIMICIFUGA RACEMOSA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:02
Data point term sent to Coder	System	01 Oct 2020 21:45:14
User entered 'Black Cohosh'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Vasomotor Symptoms'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '540'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

FDA-CBER-2022-1614-1613491

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2018'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

FDA-CBER-2022-1614-1613495

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:44:44

FDA-CBER-2022-1614-1613497

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	01 Oct 2020 21:44:44

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 16:59:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 16:59:07
Data point term sent to Coder	System	22 Jan 2021 16:57:41
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 16:56:45
User entered 'influenza vaccine' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:56:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:46:49
Data point term sent to Coder	System	01 Oct 2020 21:46:14
User entered 'Flu Shot'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

FDA-CBER-2022-1614-1613502

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Influenza Prophylaxis'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:38:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:15:31
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:15:16
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:28:55
User entered '1'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

FDA-CBER-2022-1614-1613504

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mL (mL)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

FDA-CBER-2022-1614-1613505

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once (ONCE)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '22 Sep 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

FDA-CBER-2022-1614-1613511

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '22 Sep 2020'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User entered empty.	System	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User entered empty.	System	01 Oct 2020 21:45:34

FDA-CBER-2022-1614-1613517

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:40:44
User entered empty.	System	01 Oct 2020 21:45:34

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 10:22:34
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' answered with 'subject does not know dose of med' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:14:36
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:44:51
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 14:59:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 14:59:03
Data point term sent to Coder	System	30 Nov 2020 14:57:32
User entered 'Clobetasol Propionate'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Lichen Sclerosus'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:44:08
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' answered with 'ok' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:55:21
User entered '1' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:54:53
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:12:50
User entered 'NA'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Per CDM: Please review "dose unit is other, specify" field and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:44:10
Query 'Per CDM: Please review "dose unit is other, specify" field and update accordingly. Else clarify.' answered with 'ok' (Site from DM).	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:55:25
User entered 'application' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	09 Dec 2020 15:54:53
User opened query 'Per CDM: Please review "dose unit is other, specify" field and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:15:21
User entered 'NA'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Twice weekly'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'un UNK 2018'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 14:57:44
User entered 'No (N)'		30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Nov 2020 14:57:44
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Nov 2020 14:57:30
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	30 Nov 2020 14:57:30

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered empty.	System	30 Nov 2020 14:57:30

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US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: LETROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 09:24:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 09:24:13
Data point term sent to Coder	System	30 Nov 2020 15:30:13
User entered 'Letrozole'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Stage 1 Breast Cancer'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '2.5'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

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US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Dec 2020 21:55:43
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 21:03:44
User entered '01 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 15:29:43

US3272031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 15:29:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	30 Nov 2020 15:29:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:22:39

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '1'	System	30 Nov 2020 15:29:43

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '804 (804)'	System	30 Nov 2020 15:29:43

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:22:39

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:26:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 17:11:19

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:22:39

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '26 Aug 2020'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:22:39

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Lumpectomy'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Adverse Event (AE)'	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	27 Aug 2020 13:27:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:22:39

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:32:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '5 Aug 2020'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:22:39

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:32:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Biopsy on Left Breast'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:22:39

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:32:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Diagnostic (DIAGNOSTIC)'	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:22:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:32:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	30 Sep 2020 18:42:52

US3272031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:22:39

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '1 Sep 2020'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:06

Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 16:22:39
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Other (OTHER)'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:06

US3272031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Subject undergoing cancer treatment. Subject still in study for safety followup'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:06

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:52:04
User closed query 'Data is required. Please complete.' (Site from System).		23 Dec 2020 11:25:52
Query 'Data is required. Please complete.' answered with 'data entered in error' (Site from System).	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 21:55:51
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 21:55:43
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 21:55:43
User entered '1 Sep 2020'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:39

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:52:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 11:25:55
Query 'Data is required. Please complete.' answered with 'data entered in errror ' (Site from System).	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 21:55:58
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 21:55:43
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 21:55:43
User entered 'Other (OTHER)'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

US3272031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered 'SUBJECT NO LONGER WISHES TO BE IN STUDY CAME IN FOR UNBLINDING APPOINTMENT AND SIGNED NEW CONSENT THAT SHE NO LONGER WISHED TO CONTINUE IN STUDY and was unblinded as well.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:52:51
User entered 'Subject no longer wishes to be in study came in for unblinding appointment nand was unblinded and signed new consent that she no longer wished to continue in study.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 16:52:04
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 21:55:43
User entered 'Subject undergoing cancer treatment. Subject only in study for safety followup'	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

US3272031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:39

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:22:39

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 16:22:39
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	16 Dec 2020 21:03:44

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613584

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

FDA-CBER-2022-1614-1613590

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

FDA-CBER-2022-1614-1613592

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613600

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613601

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:22:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered '19/Aug/2020 13:16'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:22:39

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered '1'		19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613616

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613621

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

FDA-CBER-2022-1614-1613622

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:22:39
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '27/Aug/2020 12:20'	System	27 Aug 2020 16:20:04

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:22:39
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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '1'		27 Aug 2020 16:20:04

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613636

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613638

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:22:39

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 16:22:39
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '09/Sep/2020 21:14'	System	10 Sep 2020 01:14:22

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:22:39

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
User entered '1'		10 Sep 2020 01:14:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'USA-US070-2020-MRNA-1273-P301000001'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'No (N)'	System	19 Aug 2020 17:15:36

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
Reviewed for Safety.		19 Aug 2020 17:16:05
User entered 'Yes (Y)'	System	19 Aug 2020 17:15:36

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Adam'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613652

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Brosz'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered '2444 W. Faidley Ave'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '2444 W Faidley Ave'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

FDA-CBER-2022-1614-1613654

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'Grand Island'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered 'Grand Island, NE 68803'	Kayla Flege (b) (4)	06 Sep 2020 18:40:05
	(b) (4)	

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:30:02
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:04
Amendment Manager: User entered 'NE'	System	14 Sep 2020 21:42:04
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 01:14:04
User entered '68803'	Kayla Flege (b) (4) (b) (4)	06 Sep 2020 18:40:05

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:18:28
Reviewed for Safety.	(b) (4), (b) (6)	27 Aug 2020 16:19:11
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:14:08
User entered 'US' (non-conformant).	System	19 Aug 2020 17:16:15

US3272031
Folder: SAE USA-US070-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 09 Jun 2021 16:22:39
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User entered '4'	System	15 Sep 2020 13:30:13
User entered '3'	System	10 Sep 2020 01:14:22
Signature has been broken.	System	27 Aug 2020 16:20:04
User entered '2'	System	27 Aug 2020 16:20:04
User signature succeeded.	Adam Brosz (b) (4)	21 Aug 2020 19:39:01
User entered '1'	System	19 Aug 2020 17:16:15

US3272031

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:22:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '15/Sep/2020 09:30'	System	15 Sep 2020 13:30:13

Folder: SAE USA-US070-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:22:39

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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:57:36
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 13:30:13

FDA-CBER-2022-1614-1613661