

US3032320 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:55:41

All time stamps listed in this document are displayed in GMT

US3032320

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

[Participant ID](#)

US3032320

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

US3032320

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3032320

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3032320

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032320

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032320

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Were any significant conditions reported?

Yes ☒

No ☐

US3032320

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3032320

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3032320

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN OCT 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 1994
Stop date completely unknown	False
Start Month and Year (derived)	OCT 1994
Start Year (derived)	1994
Stop Month and Year (derived)	OCT 1994
Stop Year (derived)	1994

US3032320

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

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

US3032320

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

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

US3032320

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Condition	DEVIATED SEPTUM REPAIR
Start date (dd MMM yyyy)	UN OCT 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 1994
Stop date completely unknown	False
Start Month and Year (derived)	OCT 1994
Start Year (derived)	1994
Stop Month and Year (derived)	OCT 1994
Stop Year (derived)	1994

US3032320

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032320

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:53:27

Generated On: 11 Aug 2021 21:55:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 11:48
Height (xxx.x)	180.3 cm
Weight (xxx.x)	82.3 kg
BMI (xxx.x)	25.31677 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

US3032320

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3032320

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3032320

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

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	

US3032320

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3032320

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 06 Nov 2020 17:49:18

Generated On: 11 Aug 2021 21:55:41

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107374

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Oct 2020 19:45:52

Generated On: 11 Aug 2021 21:55:41

Height	ND - Not Done
Weight	ND - Not Done

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Oct 2020 19:45:52

Generated On: 11 Aug 2021 21:55:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 11:48
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Oct 2020 19:45:52

Generated On: 11 Aug 2021 21:55:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3032320

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 12:42

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

US3032320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 AUG 2020
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	22 AUG 2020 12:15

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	22 AUG 2020 12:05
Nasopharyngeal Swab 2	No		

US3032320

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

97.9 °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

22 AUG 2020 13:17

PC Open Date & Time

22 AUG 2020 13:02

PC Close Date & Time

22 AUG 2020 15:32

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	22 AUG 2020 22:18
PC Open Date & Time	22 AUG 2020 16:27
PC Close Date & Time	23 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 15:15

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

24 AUG 2020 20:27

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

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

97.4 °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

25 AUG 2020 23:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 20:25

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 19:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

22 AUG 2020 13:18

PC Open Date & Time

22 AUG 2020 13:02

PC Close Date & Time

22 AUG 2020 15:32

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

22 AUG 2020 22:15

PC Open Date & Time

22 AUG 2020 16:27

PC Close Date & Time

23 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 15:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:27

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 23:45

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 20:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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 ☐

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 13:19
PC Open Date & Time	22 AUG 2020 13:02
PC Close Date & Time	22 AUG 2020 15:32

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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 ☐

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 22:16
PC Open Date & Time	22 AUG 2020 16:27
PC Close Date & Time	23 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

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 ☒

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 15:14
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

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 ☒

PRODUCTION RELEASE (v12.003

50 of 1027

EAB) (1725)

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 20:28
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

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 ☒

PRODUCTION RELEASE (v12.003

52 of 1027

EAB) (1725)

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:46
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

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 ☒

PRODUCTION RELEASE (v12.003

54 of 1027

EAB) (1725)

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:27
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

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 ☒

PRODUCTION RELEASE (v12.003

56 of 1027

EAB) (1725)

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 19:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

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 ☒

PRODUCTION RELEASE (v12.003

58 of 1027

EAB) (1725)

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:07
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3032320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	12:47 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:47
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

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?

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?

US3032320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

13:15 (24 HR)

Collection date and time (derived)

21 SEP 2020 13:15

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:02	21 SEP 2020 13:02
Nasopharyngeal Swab 2	No		

US3032320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 18:14:08

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:53:27

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:53:27

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:53:27

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:53:27

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:28
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3032320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

12:46 (24 HR)

Collection date and time (derived)

16 OCT 2020 12:46

US3032320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 15:06:10

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 10:03:45
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

29 OCT 2020 05:43:13

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

05 NOV 2020 09:14:32

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 09:29:04
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 08:22:30
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 05:39:51

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

07 DEC 2020 08:38:01

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

14 DEC 2020 03:55:06

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 09:49:57
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 07:19:58

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

04 JAN 2021 05:49:10

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

11 JAN 2021 13:43:10

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

18 JAN 2021 10:52:51

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3032320

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:55:41

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

US3032320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:56:34

Generated On: 11 Aug 2021 21:55:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032320

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:56:34

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:41:20

Generated On: 11 Aug 2021 21:55:41

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

US3032320

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:41:20

Generated On: 11 Aug 2021 21:55:41

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3032320

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:55:41

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3032320

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:55:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3032320

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

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:41:20

Generated On: 11 Aug 2021 21:55:41

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID UNBLND_DECIDE

US3032320

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 18:08:42

Generated On: 11 Aug 2021 21:55:41

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	7 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3032320

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:41:20

Generated On: 11 Aug 2021 21:55:41

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3032320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Mar 2021 21:41:20

Generated On: 11 Aug 2021 21:55:41

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3032320

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

AEID	USA-US032-2020-MRNA-1273-P30 1000004
Adverse event	SARS-COV-2 INFECTION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 AUG 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	22 AUG 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 AUG 2020
End time (00:00-23:59)	08:01 (24 HR)
AE End Date and Time (derived)	22 AUG 2020 08:01
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

112 of 1027

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT TESTED POSITIVE AT FIRST VISIT. SUBJECT NEVER EXPERIENCED SYMPTOMS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

113 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

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

Yes ☒

No ☐

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

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

Name of Medication BREO ELLIPTA (FLUTICASONE
FUROATE & VILANTEROL)

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: ASTHMA
(MILD)

Dose per administration 200/25

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

115 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 50

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

117 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

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 ☐

PRODUCTION RELEASE (v12.003

119 of 1027

EAB) (1725)

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

Name of Medication SUDAFED (PSEUDOEPHEDRINE HCL)

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 60

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)

121 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

123 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

Name of Medication MODERNA MRNA-1273
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS AGAINST
COVID-19

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

125 of 1027

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:17:43

Generated On: 11 Aug 2021 21:55:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3032320

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Dec 2020 19:49:16

Generated On: 11 Aug 2021 21:55:41

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Apr 2021 19:37:27

Generated On: 11 Aug 2021 21:55:41

Date of study discontinuation/completion (dd MMM yyyy) 7 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SUBJECT RECEIVED VACCINE THROUGH WORK.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

SAEID	USA-US032-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

SAEID	USA-US032-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/SEP/2020 08:34
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

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Sep 2020 18:14:07

Generated On: 11 Aug 2021 21:55:41

SAEID	USA-US032-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/SEP/2020 12:40
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

US3032320 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032320

Form: Participant Creation

Generated On: 11 Aug 2021 21:55:41

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
DataPoint Verified.		14 Apr 2021 15:48:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'US3032320'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:59:08

US3032320

Form: Participant Creation

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:49:57

US3032320

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:59:10

US3032320

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:49:57

US3032320

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'SCRN'	System	22 Aug 2020 17:49:57

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '(b) (6)1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:59:11

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '61'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'YEARS'	System	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '61'	System	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Male (M)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'I'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32
	(b) (4)	

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:32

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Aug 2020'	System	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2020'	System	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Amendment 2 (2)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41
	(b) (4)	

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:41

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:59:10

US3032320

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:55:41

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:55:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:46

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:58:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:58:23
Data point term sent to Coder	System	22 Aug 2020 18:57:38
User entered 'asthma'	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
Signature has been broken.	Linden DeBoer (b) (4)	25 Nov 2020 21:05:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2018'	System	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2018'	System	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 18:57:29

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
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.	(b) (4) Coder Import (b) (4)	22 Aug 2020 18:59:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:59:24
Data point term sent to Coder	System	22 Aug 2020 18:58:39
User entered 'seasonal allergies'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06
	(b) (4)	

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2000'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06
	(b) (4)	

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2000'	System	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2000'	System	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 18:58:06

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:25
Data point term sent to Coder	System	22 Aug 2020 18:59:41
User entered 'Deviated septum'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un Oct 1994'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un Oct 1994'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Oct 1994'	System	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1994'	System	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Oct 1994'	System	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1994'	System	22 Aug 2020 18:58:56

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:24
Data point term sent to Coder	System	22 Aug 2020 18:59:42
User entered 'cholecystectomy'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2006'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21
	(b) (4)	

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2006'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2006'	System	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2006'	System	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2006'	System	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2006'	System	22 Aug 2020 18:59:21

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:00:44
Data point term sent to Coder	System	22 Aug 2020 18:59:42
User entered 'gall stones'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2006'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 2006'	Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2006'	System	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2006'	System	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 2006'	System	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '2006'	System	22 Aug 2020 18:59:34

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:01:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:01:14
Data point term sent to Coder	System	22 Aug 2020 19:00:42
User entered 'deviated septum repair'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un Oct 1994'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09
	(b) (4)	

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un Oct 1994'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Oct 1994'	System	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1994'	System	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Oct 1994'	System	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1994'	System	22 Aug 2020 19:00:09

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:01:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:01:14
Data point term sent to Coder	System	22 Aug 2020 19:00:42
User entered 'bilateral hearing loss'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un UNK 1980'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28
	(b) (4)	

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'Jan 1980'	System	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1980'	System	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:55:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 19:00:28

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '11:48'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 11:48'	System	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '180.3' cm	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16
DataPoint set to visible.	(b) (4) System	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '82.3' kg	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16
DataPoint set to visible.	(b) (4) System	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
Amendment Manager: User entered '25.31677'	System	17 Sep 2020 00:20:05
User entered '25.3'	System	22 Aug 2020 18:46:16
DataPoint set to visible.	System	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'kg/m2'	System	22 Aug 2020 18:46:16
DataPoint set to visible.	System	22 Aug 2020 17:50:46

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 07:27:30
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:39:30
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:39:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 15:39:24
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:34:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered '37.2' C	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '61'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'bpm'	System	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '16'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'breaths/min'	System	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '125'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
Signature has been broken.	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 15:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '74'	Kelsey Kelley (b) (4)	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:46:16

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02

US3032320

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02

US3032320

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:58

US3032320

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:58

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27
	(b) (4)	

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27
	(b) (4)	

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27
	(b) (4)	

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27
	(b) (4)	

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 17:52:27

US3032320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:07

US3032320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 17:50:07

US3032320

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'VISIT1'	System	22 Aug 2020 17:50:07

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:24:14

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '107374'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:24:14

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:24:14

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:16

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:16

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:50:16
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:16

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:50:16

US3032320

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:41

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Nov 2020 17:49:18
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	04 Nov 2020 04:55:11
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	29 Oct 2020 21:39:08
User entered 'No (N)'	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	Linden DeBoer (b) (4)	29 Oct 2020 21:39:04
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	29 Oct 2020 12:38:10
	System	19 Sep 2020 10:39:16
	System	19 Sep 2020 02:20:10

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:09:31
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:48
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:33:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered '180.3' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
	(b) (4)	
User entered '82.3' kg	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:09:31
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.'	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:48
answered with 'updated' (Site from DM).		
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:33:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered '180.3' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
	(b) (4)	
User entered '82.3' kg	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	22 Aug 2020 18:56:12
User entered '11:48' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:56:12
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	22 Aug 2020 18:47:21
User entered '13:15'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 11:48'	System	22 Aug 2020 18:56:12
User entered '22 Aug 2020 13:15'	System	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '37.2' C reason for change: Data Entry Error	(b) (4)	22 Aug 2020 18:56:12
User entered '36.6' C	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '61'	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'bpm'	System	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:56:12
User entered '15'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'breaths/min'	System	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '125' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:56:12
User entered '140'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '74' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:56:12
User entered '83'	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:09:31
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:48
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	13 Oct 2020 14:31:41
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:33:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered '180.3' cm	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:47:21

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:45:52
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	Kelsey Kelley (b) (4)	13 Oct 2020 14:31:41
	(b) (4)	
User entered '82.3' kg	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Aug 2020 18:47:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '13:15'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 13:15'	System	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '61'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'bpm'	System	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'breaths/min'	System	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '140'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '83'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 18:57:07
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	22 Aug 2020 18:57:07

US3032320

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:22

US3032320

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:51:22
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:51:12
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
Query 'Per CDM requery: Please confirm subject was indeed dosed after determining positive since it was on the same date of exposure. thanks ' canceled (Site from DM).		28 Dec 2020 12:43:46
User opened query 'Per CDM requery: Please confirm subject was indeed dosed after determining positive since it was on the same date of exposure. thanks ' (Site from DM).		28 Dec 2020 12:20:11
User closed query 'Per CDM: Please note that there is an AE for SARS-COV-2 INFECTION (AE#1) with the same date as exposure date and start time prior to treatment time (08:00). Please review and make appropriate updates, else provide clarification. ' (Site from DM).		28 Dec 2020 12:20:11
Query 'Per CDM: Please note that there is an AE for SARS-COV-2 INFECTION (AE#1) with the same date as exposure date and start time prior to treatment time (08:00). Please review and make appropriate updates, else provide clarification. ' answered with 'the subject's day 1 nasal swab returned positive and subject was asymptomatic' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 19:29:03
User opened query 'Per CDM: Please note that there is an AE for SARS-COV-2 INFECTION (AE#1) with the same date as exposure date and start time prior to treatment time (08:00). Please review and make appropriate updates, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:57:43
Data hard unlocked.		03 Dec 2020 14:55:00
Data hard locked.		03 Dec 2020 14:54:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered '12:42'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 12:42'	System	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'ONCE'	System	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 17:51:12

US3032320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:02:01
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:02:01
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '12:15'	Kelsey Kelley (b) (4)	22 Aug 2020 19:02:01

US3032320

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 12:15'	System	22 Aug 2020 19:02:01

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '22 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:02:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:02:21
	(b) (4)	

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '12:05'	Kelsey Kelley (b) (4)	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '22 Aug 2020 12:05'	System	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	22 Aug 2020 19:02:21

US3032320

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:02:40

US3032320

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '1'	System	22 Aug 2020 19:02:40

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:17:00', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'd6b55082-e952-4bfe-87e5-f91d0a25a253'	System	22 Aug 2020 18:17:27
User entered 'Yes (Y)'	System	22 Aug 2020 18:17:27

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:17:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'd6b55082-e952-4bfe-87e5-f91d0a25a253' User entered '97.9'	System	22 Aug 2020 18:17:27
	System	22 Aug 2020 18:17:27

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:17:16', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'd6b55082-e952-4bfe-87e5-f91d0a25a253'	System	22 Aug 2020 18:17:27
User entered 'No (N)'	System	22 Aug 2020 18:17:27

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:17:25', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'd6b55082-e952-4bfe-87e5-f91d0a25a253'	System	22 Aug 2020 18:17:27
User entered '22 Aug 2020 13:17'	System	22 Aug 2020 18:17:27

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 13:02'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 15:32'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:17:58', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f76015c9-b065-439c-beb6-16e620422898' User entered 'Yes (Y)'	System	23 Aug 2020 03:18:19
	System	23 Aug 2020 03:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:18:06', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f76015c9-b065-439c-beb6-16e620422898' User entered '98.0'	System	23 Aug 2020 03:18:19
	System	23 Aug 2020 03:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:18:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f76015c9-b065-439c-beb6-16e620422898' User entered 'No (N)'	System	23 Aug 2020 03:18:19
	System	23 Aug 2020 03:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:18:14', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f76015c9-b065-439c-beb6-16e620422898' User entered '22 Aug 2020 22:18'	System	23 Aug 2020 03:18:19
	System	23 Aug 2020 03:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 16:27'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 2'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:15:32', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '70d8525d-fc3b-4cc3-9fb1-2b2a83fc0982'	System	23 Aug 2020 20:16:01
User entered 'Yes (Y)'	System	23 Aug 2020 20:16:01

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:15:40', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '70d8525d-fc3b-4cc3-9fb1-2b2a83fc0982' User entered '97.6'	System	23 Aug 2020 20:16:01
	System	23 Aug 2020 20:16:01

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:15:47', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '70d8525d-fc3b-4cc3-9fb1-2b2a83fc0982'	System	23 Aug 2020 20:16:01
User entered 'No (N)'	System	23 Aug 2020 20:16:01

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:15:54', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '70d8525d-fc3b-4cc3-9fb1-2b2a83fc0982'	System	23 Aug 2020 20:16:01
User entered '23 Aug 2020 15:15'	System	23 Aug 2020 20:16:01

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 3'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:26:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f9136c92-2251-444e-af0f-99a4fc252d37' User entered 'Yes (Y)'	System	26 Aug 2020 04:45:58
	System	26 Aug 2020 04:45:58

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:04', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f9136c92-2251-444e-af0f-99a4fc252d37' User entered '97.9'	System	26 Aug 2020 04:45:58
	System	26 Aug 2020 04:45:58

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:08', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f9136c92-2251-444e-af0f-99a4fc252d37'	System	26 Aug 2020 04:45:58
User entered 'No (N)'	System	26 Aug 2020 04:45:58

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:15', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f9136c92-2251-444e-af0f-99a4fc252d37' User entered '24 Aug 2020 20:27'	System	26 Aug 2020 04:45:58
	System	26 Aug 2020 04:45:58

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 4'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:44:43', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ee110732-639b-472d-9afe-5cfd587d258c' User entered 'Yes (Y)'	System	26 Aug 2020 04:46:17
	System	26 Aug 2020 04:46:17

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:44:50', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ee110732-639b-472d-9afe-5cfd587d258c' User entered '97.4'	System	26 Aug 2020 04:46:17
	System	26 Aug 2020 04:46:17

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:44:56', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ee110732-639b-472d-9afe-5cfd587d258c' User entered 'No (N)'	System	26 Aug 2020 04:46:17
	System	26 Aug 2020 04:46:17

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:03', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ee110732-639b-472d-9afe-5cfd587d258c' User entered '25 Aug 2020 23:45'	System	26 Aug 2020 04:46:17
	System	26 Aug 2020 04:46:17

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 5'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:25:36', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3d45d09c-a21a-40f8-88ca-7c7a89a46ed4' User entered 'Yes (Y)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:25:43', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3d45d09c-a21a-40f8-88ca-7c7a89a46ed4' User entered '98.2'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:25:47', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3d45d09c-a21a-40f8-88ca-7c7a89a46ed4' User entered 'No (N)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:25:53', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3d45d09c-a21a-40f8-88ca-7c7a89a46ed4' User entered '26 Aug 2020 20:25'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 6'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:21', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1f2db418-f92e-4667-a52c-1817310fd285'	System	09 Sep 2020 23:32:49
User entered 'Yes (Y)'	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:27', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1f2db418-f92e-4667-a52c-1817310fd285' User entered '98.6'	System	09 Sep 2020 23:32:49
	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:31', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1f2db418-f92e-4667-a52c-1817310fd285'	System	09 Sep 2020 23:32:49
User entered 'No (N)'	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:36', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1f2db418-f92e-4667-a52c-1817310fd285'	System	09 Sep 2020 23:32:49
User entered '27 Aug 2020 19:00'	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 7'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:06:54', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b6644ac2-360d-4f13-808a-f9442d341387' User entered 'Yes (Y)'	System	09 Sep 2020 23:32:54
	System	09 Sep 2020 23:32:54

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:04', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b6644ac2-360d-4f13-808a-f9442d341387' User entered '96.7'	System	09 Sep 2020 23:32:54
	System	09 Sep 2020 23:32:54

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:08', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b6644ac2-360d-4f13-808a-f9442d341387' User entered 'No (N)'	System	09 Sep 2020 23:32:54
	System	09 Sep 2020 23:32:54

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:15', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b6644ac2-360d-4f13-808a-f9442d341387' User entered '28 Aug 2020 12:07'	System	09 Sep 2020 23:32:54
	System	09 Sep 2020 23:32:54

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:17:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ac39f55b-5d73-4981-b6f9-92c6b117d943'	System	22 Aug 2020 18:18:19
User entered 'None (1)'	System	22 Aug 2020 18:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:00', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ac39f55b-5d73-4981-b6f9-92c6b117d943' User entered 'No (N)'	System	22 Aug 2020 18:18:19
	System	22 Aug 2020 18:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:05', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ac39f55b-5d73-4981-b6f9-92c6b117d943' User entered 'No (N)'	System	22 Aug 2020 18:18:19
	System	22 Aug 2020 18:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:12', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ac39f55b-5d73-4981-b6f9-92c6b117d943'	System	22 Aug 2020 18:18:19
User entered 'None (1)'	System	22 Aug 2020 18:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:17', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ac39f55b-5d73-4981-b6f9-92c6b117d943'	System	22 Aug 2020 18:18:19
User entered '22 Aug 2020 13:18'	System	22 Aug 2020 18:18:19

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 13:02'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 15:32'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:14:49', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'a88cecb8-313a-4e19-a1c0-b69ed42b6cff' User entered 'None (1)'	System	23 Aug 2020 03:15:47
	System	23 Aug 2020 03:15:47

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:15:13', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'a88cecb8-313a-4e19-a1c0-b69ed42b6cff' User entered 'No (N)'	System	23 Aug 2020 03:15:47
	System	23 Aug 2020 03:15:47

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:15:19', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'a88cecb8-313a-4e19-a1c0-b69ed42b6cff' User entered 'No (N)'	System	23 Aug 2020 03:15:47
	System	23 Aug 2020 03:15:47

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:15:27', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'a88cecb8-313a-4e19-a1c0-b69ed42b6cff' User entered 'None (1)'	System	23 Aug 2020 03:15:47
	System	23 Aug 2020 03:15:47

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:15:41', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'a88cecb8-313a-4e19-a1c0-b69ed42b6cff' User entered '22 Aug 2020 22:15'	System	23 Aug 2020 03:15:47
	System	23 Aug 2020 03:15:47

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 16:27'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 2'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:20', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3534caf9-17a7-440b-83a3-a495f9ba2fdc'	System	23 Aug 2020 20:14:43
User entered 'None (1)'	System	23 Aug 2020 20:14:43

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:24', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3534caf9-17a7-440b-83a3-a495f9ba2fdc' User entered 'No (N)'	System	23 Aug 2020 20:14:43
	System	23 Aug 2020 20:14:43

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:30', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3534caf9-17a7-440b-83a3-a495f9ba2fdc' User entered 'No (N)'	System	23 Aug 2020 20:14:43
	System	23 Aug 2020 20:14:43

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:36', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3534caf9-17a7-440b-83a3-a495f9ba2fdc' User entered 'None (1)'	System	23 Aug 2020 20:14:43
	System	23 Aug 2020 20:14:43

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:48', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3534caf9-17a7-440b-83a3-a495f9ba2fdc' User entered '23 Aug 2020 15:13'	System	23 Aug 2020 20:14:43
	System	23 Aug 2020 20:14:43

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 3'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:25', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4cd5134a-ea48-407b-8e1a-ab984ec8f731' User entered 'None (1)'	System	26 Aug 2020 04:46:04
	System	26 Aug 2020 04:46:04

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:29', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4cd5134a-ea48-407b-8e1a-ab984ec8f731' User entered 'No (N)'	System	26 Aug 2020 04:46:04
	System	26 Aug 2020 04:46:04

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:32', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4cd5134a-ea48-407b-8e1a-ab984ec8f731' User entered 'No (N)'	System	26 Aug 2020 04:46:04
	System	26 Aug 2020 04:46:04

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:41', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4cd5134a-ea48-407b-8e1a-ab984ec8f731' User entered 'None (1)'	System	26 Aug 2020 04:46:04
	System	26 Aug 2020 04:46:04

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:48', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4cd5134a-ea48-407b-8e1a-ab984ec8f731' User entered '24 Aug 2020 20:27'	System	26 Aug 2020 04:46:04
	System	26 Aug 2020 04:46:04

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 4'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '03f379f5-d7a5-4446-bea4-057d4fe54821'	System	26 Aug 2020 04:46:18
User entered 'None (1)'	System	26 Aug 2020 04:46:18

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:14', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '03f379f5-d7a5-4446-bea4-057d4fe54821' User entered 'No (N)'	System	26 Aug 2020 04:46:18
	System	26 Aug 2020 04:46:18

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:18', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '03f379f5-d7a5-4446-bea4-057d4fe54821' User entered 'No (N)'	System	26 Aug 2020 04:46:18
	System	26 Aug 2020 04:46:18

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:25', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '03f379f5-d7a5-4446-bea4-057d4fe54821'	System	26 Aug 2020 04:46:18
User entered 'None (1)'	System	26 Aug 2020 04:46:18

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:34', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '03f379f5-d7a5-4446-bea4-057d4fe54821' User entered '25 Aug 2020 23:45'	System	26 Aug 2020 04:46:18
	System	26 Aug 2020 04:46:18

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 5'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:25:59', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '5f0d93d9-ca2e-4c8b-bf45-ca0be68c3ed8'	System	01 Sep 2020 15:34:15
User entered 'None (1)'	System	01 Sep 2020 15:34:15

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:07', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '5f0d93d9-ca2e-4c8b-bf45-ca0be68c3ed8' User entered 'No (N)'	System	01 Sep 2020 15:34:15
	System	01 Sep 2020 15:34:15

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:11', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '5f0d93d9-ca2e-4c8b-bf45-ca0be68c3ed8' User entered 'No (N)'	System	01 Sep 2020 15:34:15
	System	01 Sep 2020 15:34:15

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:16', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '5f0d93d9-ca2e-4c8b-bf45-ca0be68c3ed8'	System	01 Sep 2020 15:34:15
User entered 'None (1)'	System	01 Sep 2020 15:34:15

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:24', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '5f0d93d9-ca2e-4c8b-bf45-ca0be68c3ed8' User entered '26 Aug 2020 20:26'	System	01 Sep 2020 15:34:15
	System	01 Sep 2020 15:34:15

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 6'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:46', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '149e45cd-0d36-43b8-a49d-a38de2a3778f'	System	09 Sep 2020 23:32:49
User entered 'None (1)'	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:50', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '149e45cd-0d36-43b8-a49d-a38de2a3778f' User entered 'No (N)'	System	09 Sep 2020 23:32:49
	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:53', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '149e45cd-0d36-43b8-a49d-a38de2a3778f' User entered 'No (N)'	System	09 Sep 2020 23:32:49
	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:00:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '149e45cd-0d36-43b8-a49d-a38de2a3778f' User entered 'None (1)'	System	09 Sep 2020 23:32:49
	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:02', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '149e45cd-0d36-43b8-a49d-a38de2a3778f' User entered '27 Aug 2020 19:01'	System	09 Sep 2020 23:32:49
	System	09 Sep 2020 23:32:49

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 7'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:08:03', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '23c4827b-7b4d-4d8e-9080-15c669baaf89'	System	09 Sep 2020 23:32:55
User entered 'None (1)'	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:08:06', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '23c4827b-7b4d-4d8e-9080-15c669baaf89' User entered 'No (N)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:08:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '23c4827b-7b4d-4d8e-9080-15c669baaf89' User entered 'No (N)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:08:14', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '23c4827b-7b4d-4d8e-9080-15c669baaf89' User entered 'None (1)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:08:17', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '23c4827b-7b4d-4d8e-9080-15c669baaf89' User entered '28 Aug 2020 12:08'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:28', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:36', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:39', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:42', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:46', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:18:54', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'None (0)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:19:01', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered 'No (N)'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T13:19:11', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '53f74d65-a897-4c15-ae21-5c8246c28a3c' User entered '22 Aug 2020 13:19'	System	22 Aug 2020 18:19:14
	System	22 Aug 2020 18:19:14

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 13:02'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 15:32'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:15:53', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'No interference with activity (1)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:00', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c'	System	23 Aug 2020 03:16:55
User entered 'No interference with activity (1)'	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:03', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'None (0)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:07', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'None (0)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'None (0)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:23', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'None (0)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:27', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered 'No (N)'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-22T22:16:50', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '38791894-6df6-4ad0-9b3f-08bae7cb871c' User entered '22 Aug 2020 22:16'	System	23 Aug 2020 03:16:55
	System	23 Aug 2020 03:16:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '22 Aug 2020 16:27'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 2'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:13:55', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:00', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:11', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:15', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:20', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:23', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'None (0)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:29', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered 'No (N)'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-23T15:14:41', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '3e7422a7-b428-4454-8c11-0669c5c60f2f' User entered '23 Aug 2020 15:14'	System	23 Aug 2020 20:14:46
	System	23 Aug 2020 20:14:46

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 3'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:54', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:27:58', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:01', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:06', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:14', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'None (0)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:20', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered 'No (N)'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-24T20:28:29', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '777a1245-210f-404d-9d2e-eafb744f423e' User entered '24 Aug 2020 20:28'	System	26 Aug 2020 04:46:11
	System	26 Aug 2020 04:46:11

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 4'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:40', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:45', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:49', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:53', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:55', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:45:59', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'None (0)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:46:05', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered 'No (N)'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-25T23:46:09', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b8108f4a-24f5-4b4f-b428-eede6868d5a9' User entered '25 Aug 2020 23:46'	System	01 Sep 2020 15:34:13
	System	01 Sep 2020 15:34:13

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 5'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:30', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:35', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:38', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:41', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:43', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:46', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745' User entered 'None (0)'	System	01 Sep 2020 15:34:18
	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:26:52', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745'	System	01 Sep 2020 15:34:18
User entered 'No (N)'	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-26T20:27:01', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'b3856285-6eac-4853-a9c4-6f1f1350f745'	System	01 Sep 2020 15:34:18
User entered '26 Aug 2020 20:27'	System	01 Sep 2020 15:34:18

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 6'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:08', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862'	System	09 Sep 2020 23:32:51
User entered 'None (0)'	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862'	System	09 Sep 2020 23:32:51
User entered 'None (0)'	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:13', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862'	System	09 Sep 2020 23:32:51
User entered 'None (0)'	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:16', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862' User entered 'None (0)'	System	09 Sep 2020 23:32:51
	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:19', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862' User entered 'None (0)'	System	09 Sep 2020 23:32:51
	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:22', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862' User entered 'None (0)'	System	09 Sep 2020 23:32:51
	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:28', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862'	System	09 Sep 2020 23:32:51
User entered 'No (N)'	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-27T19:01:32', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'cf19e0be-eba0-4313-8c12-b7af10ebb862'	System	09 Sep 2020 23:32:51
User entered '27 Aug 2020 19:01'	System	09 Sep 2020 23:32:51

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 7'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:20', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:25', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:28', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:32', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:35', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:37', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'None (0)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:42', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered 'No (N)'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-08-28T12:07:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '434dc09b-9545-4092-b000-614bdc9ed081' User entered '28 Aug 2020 12:07'	System	09 Sep 2020 23:32:55
	System	09 Sep 2020 23:32:55

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:51:12

US3032320

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:55:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	01 Sep 2020 12:20:18

US3032320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '31 Aug 2020'	Linden DeBoer (b) (4)	01 Sep 2020 12:20:18

US3032320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	01 Sep 2020 12:20:18

US3032320

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Linden DeBoer (b) (4)	01 Sep 2020 12:20:18

US3032320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	01 Sep 2020 12:20:21

US3032320

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	01 Sep 2020 12:20:21

US3032320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:07

US3032320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 03:09:21
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'		09 Sep 2020 15:24:30
answered with 'correct as entered subject did not answer on previous attempt.' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 15:24:07
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 15:24:07

US3032320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:07

US3032320

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:07

US3032320

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:36

US3032320

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered 'I'	System	09 Sep 2020 15:24:36

US3032320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 18:47:40

US3032320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '14 Sep 2020'	Kelsey Kelley (b) (4)	15 Sep 2020 18:47:40

US3032320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	15 Sep 2020 18:47:40

US3032320

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:47:40

US3032320

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	15 Sep 2020 18:48:16

US3032320

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered 'I'	System	15 Sep 2020 18:48:16

US3032320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:04:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:02
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:04:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'VISIT2'	System	21 Sep 2020 19:04:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '12:47'	Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '21 Sep 2020 12:47'	System	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '36.8' C	Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '67'	Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'bpm'	System	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'breaths/min'	System	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '132'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '85'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:04:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	21 Sep 2020 19:04:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:35
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:35

US3032320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:44

US3032320

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '21 Sep 2020'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:44

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User closed query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' (Site from DM).		02 Dec 2020 14:24:59
Query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' answered with 'FORM UPDATED' (Site from DM).	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 16:24:18
User opened query 'Per CDM: If the subject is not going to receive any further IP doses, the Dosing Discontinuation form needs to be completed. Kindly review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:51:42
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:05:06
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:05:06
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:05:02
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:02

US3032320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:07:08
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:07:08
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '13:15'	Kelsey Kelley (b) (4)	21 Sep 2020 19:07:08

US3032320

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '21 Sep 2020 13:15'	System	21 Sep 2020 19:07:08

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '21 Sep 2020'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '13:02'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '21 Sep 2020 13:02'	System	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	Kelsey Kelley (b) (4)	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered empty.	System	21 Sep 2020 19:05:23

US3032320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	21 Sep 2020 19:05:27
	(b) (4)	

US3032320

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	21 Sep 2020 19:05:27

US3032320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:17:42

US3032320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:17:42

US3032320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:17:42

US3032320

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:17:42

US3032320

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:17:46

US3032320

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered 'I'	System	06 Oct 2020 14:17:46

US3032320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:18:01

US3032320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:18:01

US3032320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:18:01

US3032320

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:18:01

US3032320

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:53:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:18:06

US3032320

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	06 Oct 2020 14:18:06

US3032320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 15:58:18
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:58:02
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:02
	(b) (4)	

US3032320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:18
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:02
	(b) (4)	

US3032320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:02

US3032320

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered empty.	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:02

US3032320

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:58:30

US3032320

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	19 Oct 2020 15:58:30

US3032320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:59:58

US3032320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '16 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 15:59:58
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	19 Oct 2020 15:59:58

US3032320

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'VISIT3'	System	19 Oct 2020 15:59:58

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '16 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '12:28'	Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '16 Oct 2020 12:28'	System	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '36.7' C	Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '69'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'bpm'	System	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '14'	Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'breaths/min'	System	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '134'	Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '83'	Kelsey Kelley (b) (4)	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'mmHg'	System	19 Oct 2020 16:00:37

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02

US3032320

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02

US3032320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Oct 2020 16:01:14

US3032320

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '16 Oct 2020'	Kelsey Kelley (b) (4)	19 Oct 2020 16:01:14

US3032320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Oct 2020 16:01:44

US3032320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '16 Oct 2020'	Kelsey Kelley (b) (4)	19 Oct 2020 16:01:44

US3032320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered '12:46'	Kelsey Kelley (b) (4)	19 Oct 2020 16:01:44

US3032320

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered '16 Oct 2020 12:46'	System	19 Oct 2020 16:01:44

US3032320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 15:06:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 16:02:00
	(b) (4)	

US3032320

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	19 Oct 2020 16:02:00

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 64'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-23T10:03:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1c616863-cc0a-427f-8665-19983e0e224b' User entered 'No (N)'	System	23 Oct 2020 15:03:58
	System	23 Oct 2020 15:03:58

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

Have you been exposed to someone with 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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-23T10:03:19', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1c616863-cc0a-427f-8665-19983e0e224b' User entered 'Yes (Y)'	System	23 Oct 2020 15:03:58
	System	23 Oct 2020 15:03:58

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Please 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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-23T10:03:33', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1c616863-cc0a-427f-8665-19983e0e224b'	System	23 Oct 2020 15:03:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 15:03:58

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-23T10:03:45', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '1c616863-cc0a-427f-8665-19983e0e224b' User entered '23 Oct 2020 10:03:45'	System	23 Oct 2020 15:03:58
	System	23 Oct 2020 15:03:58

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 71'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-29T05:42:52', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'dafbe85a-9d26-405e-87ba-397efa4f78f2'	System	29 Oct 2020 10:43:59
User entered 'No (N)'	System	29 Oct 2020 10:43:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Have you been exposed to someone with 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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-29T05:43:01', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'dafbe85a-9d26-405e-87ba-397efa4f78f2'	System	29 Oct 2020 10:43:59
User entered 'No (N)'	System	29 Oct 2020 10:43:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-10-29T05:43:13', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'dafbe85a-9d26-405e-87ba-397efa4f78f2' User entered '29 Oct 2020 05:43:13'	System	29 Oct 2020 10:43:59
	System	29 Oct 2020 10:43:59

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 78'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-05T09:14:14', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '2758ea26-c955-49fc-aa56-b27cb9e89056'	System	05 Nov 2020 15:14:38
User entered 'No (N)'	System	05 Nov 2020 15:14:38

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

Have you been exposed to someone with 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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-05T09:14:20', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '2758ea26-c955-49fc-aa56-b27cb9e89056'	System	05 Nov 2020 15:14:38
User entered 'No (N)'	System	05 Nov 2020 15:14:38

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-05T09:14:32', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '2758ea26-c955-49fc-aa56-b27cb9e89056' User entered '05 Nov 2020 09:14:32'	System	05 Nov 2020 15:14:38
	System	05 Nov 2020 15:14:38

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered 'Day 92'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-19T09:28:46', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4d470721-9c97-4b0f-a654-1ba9e7d5e006'	System	19 Nov 2020 15:29:11
User entered 'No (N)'	System	19 Nov 2020 15:29:11

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

Have you been exposed to someone with 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)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-19T09:28:54', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4d470721-9c97-4b0f-a654-1ba9e7d5e006'	System	19 Nov 2020 15:29:11
User entered 'No (N)'	System	19 Nov 2020 15:29:11

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-19T09:29:04', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4d470721-9c97-4b0f-a654-1ba9e7d5e006' User entered '19 Nov 2020 09:29:04'	System	19 Nov 2020 15:29:11
	System	19 Nov 2020 15:29:11

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 17:51:12

US3032320

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:11:34
Data entry locked.	System	22 Aug 2020 17:51:12
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 17:51:12

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-25T08:22:19', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4c071efa-da1c-45da-8c3c-5c71ffadedfb' User entered 'No (N)'	System	25 Nov 2020 14:22:34
	System	25 Nov 2020 14:22:34

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-25T08:22:23', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4c071efa-da1c-45da-8c3c-5c71ffadedfb' User entered 'No (N)'	System	25 Nov 2020 14:22:34
	System	25 Nov 2020 14:22:34

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-25T08:22:30', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '4c071efa-da1c-45da-8c3c-5c71ffadedfb' User entered '25 Nov 2020 08:22:30'	System	25 Nov 2020 14:22:34
	System	25 Nov 2020 14:22:34

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-30T05:39:35', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '905d4beb-e6bc-412e-a64b-3021404fb1ff' User entered 'No (N)'	System	30 Nov 2020 11:39:54
	System	30 Nov 2020 11:39:54

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-30T05:39:42', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '905d4beb-e6bc-412e-a64b-3021404fb1ff'	System	30 Nov 2020 11:39:54
User entered 'No (N)'	System	30 Nov 2020 11:39:54

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-11-30T05:39:51', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '905d4beb-e6bc-412e-a64b-3021404fb1ff' User entered '30 Nov 2020 05:39:51'	System	30 Nov 2020 11:39:54
	System	30 Nov 2020 11:39:54

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-07T08:37:45', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ca432453-0116-4a9f-a6d9-1263031af7ee' User entered 'No (N)'	System	07 Dec 2020 14:38:05
	System	07 Dec 2020 14:38:05

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-07T08:37:52', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ca432453-0116-4a9f-a6d9-1263031af7ee' User entered 'No (N)'	System	07 Dec 2020 14:38:05
	System	07 Dec 2020 14:38:05

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-07T08:38:01', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'ca432453-0116-4a9f-a6d9-1263031af7ee' User entered '07 Dec 2020 08:38:01'	System	07 Dec 2020 14:38:05
	System	07 Dec 2020 14:38:05

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-14T03:54:46', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '85ff8e69-d28c-455a-ae84-7717fd0f926d' User entered 'No (N)'	System	14 Dec 2020 09:55:10
	System	14 Dec 2020 09:55:10

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-14T03:54:55', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '85ff8e69-d28c-455a-ae84-7717fd0f926d' User entered 'No (N)'	System	14 Dec 2020 09:55:10
	System	14 Dec 2020 09:55:10

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-14T03:55:06', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '85ff8e69-d28c-455a-ae84-7717fd0f926d' User entered '14 Dec 2020 03:55:06'	System	14 Dec 2020 09:55:10
	System	14 Dec 2020 09:55:10

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-21T09:49:44', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f40fef4e-92df-4866-97d1-86d158c5b59c'	System	21 Dec 2020 15:50:06
User entered 'No (N)'	System	21 Dec 2020 15:50:06

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-21T09:49:50', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f40fef4e-92df-4866-97d1-86d158c5b59c'	System	21 Dec 2020 15:50:06
User entered 'No (N)'	System	21 Dec 2020 15:50:06

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-21T09:49:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f40fef4e-92df-4866-97d1-86d158c5b59c' User entered '21 Dec 2020 09:49:57'	System	21 Dec 2020 15:50:06
	System	21 Dec 2020 15:50:06

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-28T07:19:40', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f2c05918-6113-4eb6-8cd4-8063398ef782'	System	28 Dec 2020 13:20:04
User entered 'No (N)'	System	28 Dec 2020 13:20:04

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-28T07:19:45', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f2c05918-6113-4eb6-8cd4-8063398ef782'	System	28 Dec 2020 13:20:04
User entered 'No (N)'	System	28 Dec 2020 13:20:04

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2020-12-28T07:19:58', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: 'f2c05918-6113-4eb6-8cd4-8063398ef782' User entered '28 Dec 2020 07:19:58'	System	28 Dec 2020 13:20:04
	System	28 Dec 2020 13:20:04

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-04T05:48:53', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '7045a8c8-7fa2-489e-93f4-de534fd099ff' User entered 'No (N)'	System	04 Jan 2021 11:49:17
	System	04 Jan 2021 11:49:17

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-04T05:49:02', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '7045a8c8-7fa2-489e-93f4-de534fd099ff'	System	04 Jan 2021 11:49:17
User entered 'No (N)'	System	04 Jan 2021 11:49:17

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-04T05:49:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '7045a8c8-7fa2-489e-93f4-de534fd099ff' User entered '04 Jan 2021 05:49:10'	System	04 Jan 2021 11:49:17
	System	04 Jan 2021 11:49:17

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-11T13:42:51', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '47822f47-db2f-41e4-b56d-319fa8d5e3a5'	System	11 Jan 2021 19:43:13
User entered 'No (N)'	System	11 Jan 2021 19:43:13

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-11T13:42:57', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '47822f47-db2f-41e4-b56d-319fa8d5e3a5'	System	11 Jan 2021 19:43:13
User entered 'No (N)'	System	11 Jan 2021 19:43:13

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-11T13:43:10', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '47822f47-db2f-41e4-b56d-319fa8d5e3a5' User entered '11 Jan 2021 13:43:10'	System	11 Jan 2021 19:43:13
	System	11 Jan 2021 19:43:13

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-18T10:52:41', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '8881c778-7540-4003-903b-9de32c718751'	System	18 Jan 2021 16:52:56
User entered 'No (N)'	System	18 Jan 2021 16:52:56

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-18T10:52:47', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '8881c778-7540-4003-903b-9de32c718751'	System	18 Jan 2021 16:52:56
User entered 'No (N)'	System	18 Jan 2021 16:52:56

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35A1EB45-F1D8-4D9C-B134-9B1AE685DCDF)', Time: '2021-01-18T10:52:51', User OID: 'PatientReportedOutcome (US3032320)', ODM File OID: '8881c778-7540-4003-903b-9de32c718751' User entered '18 Jan 2021 10:52:51'	System	18 Jan 2021 16:52:56
	System	18 Jan 2021 16:52:56

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:19:37

US3032320

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:19:37
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:19:37

US3032320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	01 Dec 2020 20:59:48

US3032320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered '17 Nov 2020'	Linden DeBoer (b) (4)	01 Dec 2020 20:59:48

US3032320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	01 Dec 2020 20:59:48

US3032320

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered empty.	Linden DeBoer (b) (4)	01 Dec 2020 20:59:48

US3032320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	01 Dec 2020 20:59:53

US3032320

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:49:02
User entered 'I'	System	01 Dec 2020 20:59:53

US3032320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:34
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	17 Dec 2020 14:22:25

US3032320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:34
User entered '16 Dec 2020'	Kelsey Kelley (b) (4)	17 Dec 2020 14:22:25

US3032320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:34
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	17 Dec 2020 14:22:25

US3032320

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:22:25

US3032320

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:56:34
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	17 Dec 2020 14:22:27

US3032320

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered 'I'	System	17 Dec 2020 14:22:27

US3032320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:41:07

US3032320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:41:07

US3032320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:41:07

US3032320

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:41:07

US3032320

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:41:10

US3032320

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered empty.	System	16 Mar 2021 16:41:10

US3032320

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

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:39:45

US3032320

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

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:39:45

US3032320

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

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:39:45

US3032320

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

Form: Visit Date

Generated On: 11 Aug 2021 21:55:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered 'UNBLND_DECIDE'	System	16 Mar 2021 16:39:45

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User closed query 'Per CDM : N/A-Subject unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later ' please reconcile. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:07:46
Query 'Per CDM : N/A-Subject unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later ' please reconcile. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	08 Apr 2021 13:37:14
User opened query 'Per CDM : N/A-Subject unblinded under A5 and study discon is ticked' but 'Protocol version for participant unblinding is A6 or later ' please reconcile. ' (Site from DM).	(b) (4)	08 Apr 2021 04:45:14
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'I'	(b) (4)	
	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08
	(b) (4)	

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
Signature has been broken.	Samantha Wieseler (b) (4)	08 Apr 2021 13:36:57
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	08 Apr 2021 13:36:57
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered '7 Jan 2021'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'Placebo (Placebo)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'Placebo (Placebo)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'Placebo (Placebo)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered '1'	System	16 Mar 2021 16:40:08

US3032320

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered empty.	System	16 Mar 2021 16:40:08

US3032320

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:12

US3032320

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:40:12

US3032320

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:40:12

US3032320

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered empty.	System	16 Mar 2021 16:40:12

US3032320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:55:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered 'No (N)'	Linden DeBoer (b) (4)	16 Mar 2021 16:40:16

US3032320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:55:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:40:16

US3032320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:55:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:41:20
User entered empty.	Linden DeBoer (b) (4)	16 Mar 2021 16:40:16

US3032320

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:55:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered empty.	System	16 Mar 2021 16:40:16

US3032320

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:55:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
Signature has been broken.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 20:56:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:07:01
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	15 Sep 2020 18:48:35

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:31:14
User entered 'USA-US032-2020-mRNA-1273-P301000004'	System	16 Sep 2020 12:29:38
User entered 'New'	(b) (4), (b) (6)	16 Sep 2020 12:29:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:05:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:05:15
Data point term sent to Coder	System	25 Nov 2020 21:03:50
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'Sars-Cov-2 Infection' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
Data point term sent to Coder	System	25 Nov 2020 20:56:46
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
Data point term sent to Coder	System	23 Sep 2020 13:08:34
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 05:16:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 05:16:01
Data point term sent to Coder	System	15 Sep 2020 18:51:08
User entered 'sars-cov 2 infection'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User entered 'No (N)'	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User entered 'No (N)'	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered '22 Aug 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User entered '22 Aug 2020'	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 21:03:43
User entered '08:00' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:43
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 00:37:20
User entered '08:00' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	17 Sep 2020 00:37:20
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 18:50:38
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User entered '22 Aug 2020 08:00'	System	25 Nov 2020 21:03:43
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	23 Sep 2020 13:08:30
User entered empty.	System	23 Sep 2020 13:07:59
User entered '22 Aug 2020 08:00'	System	17 Sep 2020 00:37:20
User entered empty.	System	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User entered 'No (N)'	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	
	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User entered '22 Aug 2020'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	(b) (4)	25 Nov 2020 21:03:50
User entered '08:01' reason for change: Data Entry Error	System	25 Nov 2020 21:03:50
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	Linden DeBoer (b) (4)	25 Nov 2020 21:03:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Nov 2020 21:03:43
User entered '08:00' reason for change: Data Entry Error	System	25 Nov 2020 21:03:43
User opened query 'Data is required. Please provide.' (Site from System).	Linden DeBoer (b) (4)	25 Nov 2020 21:03:43
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 21:03:43
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
User entered empty; reason for change Data Entry Error	(b) (4)	23 Sep 2020 13:08:30
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User entered '08:08' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 13:07:59
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	17 Sep 2020 00:37:46
User closed query 'Data is required. Please provide.' (Site from System).	Kelsey Kelley (b) (4)	17 Sep 2020 00:37:46
User entered '08:00' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 00:37:29
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 00:37:29
User closed query 'Data is required. Please provide.' (Site from System).	Kelsey Kelley (b) (4)	17 Sep 2020 00:37:29
User entered '08:00' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 00:37:29
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 18:50:38
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
Query 'PV query: Please confirm stop date of the event since currently reported is the same day as onset of event.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 21:37:18
User entered '22 Aug 2020 08:01'	System	25 Nov 2020 21:03:50
User entered '22 Aug 2020 08:00'	System	25 Nov 2020 21:03:43
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'PV query: Please confirm stop date of the event since currently reported is the same day as onset of event.' (Site from Safety).	(b) (4)	
User entered '22 Aug 2020 08:08'	System	23 Sep 2020 13:07:59
User entered '22 Aug 2020 08:00'	(b) (4), (b) (6)	18 Sep 2020 18:06:53
User entered empty.		
	System	17 Sep 2020 00:37:46
	System	17 Sep 2020 00:37:29
	System	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User closed query 'Data is required. Please complete.' (Site from System).	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	17 Sep 2020 13:51:48
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	System	17 Sep 2020 13:51:48
User opened query 'Data is required. Please complete.' (Site from System).	Linden DeBoer (b) (4)	15 Sep 2020 18:50:38
User entered empty.	System	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 13:51:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 13:51:48
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 18:50:38
User entered empty.	System	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	18 Sep 2020 16:38:57
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'per protocol is + for COVID 2nd vax is held. subject was asymptomatic.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 13:54:18
User closed query 'Data is required. Please complete.' (Site from System).	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	17 Sep 2020 13:51:48
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 12:32:39
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:50:38
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User closed query 'Data is required. Please complete.' (Site from System).	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	17 Sep 2020 13:51:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	17 Sep 2020 13:51:48
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:50:38
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:58:04
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with '+ COVID 19 with no symptoms. that is documented on the dosing discontinuation page ' (Site from System).	Linden DeBoer (b) (4) (b) (4)	02 Dec 2020 22:04:47
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	02 Dec 2020 17:39:13
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		01 Dec 2020 16:23:36
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	01 Dec 2020 16:23:36
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	01 Dec 2020 16:21:22
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Sep 2020 13:07:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '1'	Kelsey Kelley (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 21:03:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 21:03:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	(b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 13:07:59
User entered empty; reason for change Data Entry Error	System	23 Sep 2020 13:07:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Linden DeBoer (b) (4)	23 Sep 2020 13:07:59
	(b) (4)	15 Sep 2020 18:50:38
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30
User entered empty.	Kelsey Kelley (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'PV query: Please confirm if the subject had the SARS-COV 2 infection prior to administration of study drug. If so, please remove the EDC as the event is not valid.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Nov 2020 21:37:33
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 21:37:31
Query 'PV query: Please confirm if the subject had the SARS-COV 2 infection prior to administration of study drug. If so, please remove the EDC as the event is not valid.' answered with 'updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 21:04:01
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 21:03:55
User entered 'Subject tested positive at first visit. Subject never experienced symptoms.' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 21:03:32
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4) (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4) (b) (4)	23 Sep 2020 13:08:30
User opened query 'PV query: Please confirm if the subject had the SARS-COV 2 infection prior to administration of study drug. If so, please remove the EDC as the event is not valid.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:08:20
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:07:35
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:50:38

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	23 Sep 2020 13:08:30
User entered '0'	Linden DeBoer (b) (4)	17 Sep 2020 13:51:48
	System	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	23 Sep 2020 13:08:30
User entered '0'	Linden DeBoer (b) (4)	15 Sep 2020 18:50:38
	System	

US3032320

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:55:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	25 Nov 2020 20:56:17
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	23 Sep 2020 13:08:30

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User closed query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:47:48
Query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' answered with 'Updated ConMed log with vaccine received outside of study' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:09:53
User opened query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:38:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 17:51:30

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	28 Sep 2020 18:14:09
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: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 07:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 07:56:51
Data point term sent to Coder	System	17 Sep 2020 00:36:46
User entered 'BREO ELLIPTA (FLUTICASONE FUROATE & vilanterol)' reason for change: New Information	Kelsey Kelley (b) (4)	17 Sep 2020 00:35:47
Data point term sent to Coder	System	17 Sep 2020 00:35:46
Coding entries removed.	Kelsey Kelley (b) (4)	17 Sep 2020 00:35:26
User entered 'BREO ELLIPTA (fluticasone furoate)' reason for change: New Information	Kelsey Kelley (b) (4)	17 Sep 2020 00:35:26
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: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:53:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:53:55
Data point term sent to Coder	System	15 Sep 2020 18:53:17
Coding entries removed.	Kelsey Kelley (b) (4)	15 Sep 2020 18:52:56

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

Name of Medication

Audit	User	Time (GMT)
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: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:07:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:07:16
Data point term sent to Coder	System	22 Aug 2020 19:06:47
User entered 'breo ellipta'	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'medical history: asthma (mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:06:46
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 00:33:40
User entered '200/25' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 00:33:30
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:07:52
User entered '200'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 18:52:56
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 18:52:56
	(b) (4)	
User entered 'mcg'	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:58:23
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Data updated.' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:53:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:52:56
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:08:14
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'un UNK 2018'	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:06:21
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 19:06:21

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:59:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:59:44
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	15 Sep 2020 18:58:36 15 Sep 2020 18:58:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:17:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:17:12
Data point term sent to Coder User entered 'flonase'	System Kelsey Kelley (b) (4)	22 Aug 2020 19:15:59 22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'medical history: SEASONAL ALLERGIES'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 18:58:24
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 18:58:24
	(b) (4)	
User entered 'MCG'	Kelsey Kelley (b) (4)	22 Aug 2020 19:15:51
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:11
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:58:36
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 18:58:24
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:06:56
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'un Jan 2019'	Kelsey Kelley (b) (4)	22 Aug 2020 19:15:51
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:15:51
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:15:51
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 19:15:51

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
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)	17 Sep 2020 00:35:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 00:35:51
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	17 Sep 2020 00:34:45 17 Sep 2020 00:34:15
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)	22 Aug 2020 19:18:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:18:13
Data point term sent to Coder User entered 'multivitamin'	System Kelsey Kelley (b) (4)	22 Aug 2020 19:16:59 22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:33:35
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:01:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:00:58
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:29:39
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User closed query 'Per CDM: Please record type of supplement (like nutritional supplement, Potassium supplement, etc.) as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 06:40:30
Query 'Per CDM: Please record type of supplement (like nutritional supplement, Potassium supplement, etc.) as appropriate.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 00:34:24
User entered 'nutritional SUPPLEMENT' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 00:34:15
User opened query 'Per CDM: Please record type of supplement (like nutritional supplement, Potassium supplement, etc.) as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 09:34:44
User entered 'supplement'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'tablet (TABLET)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:16:31
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:16:31
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'un UNK 1990'	Kelsey Kelley (b) (4)	22 Aug 2020 19:16:31
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:16:31
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:16:31
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 19:16:31

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 13:07:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 13:07:32
Data point term sent to Coder	System	17 Sep 2020 00:36:46
User closed query 'CDM-Coding: The trade name sudafed can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	System	17 Sep 2020 00:36:33
Query 'CDM-Coding: The trade name sudafed can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'data updated' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 00:36:33
User entered 'SUDAFED (pseudoephedrine HCL)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	17 Sep 2020 00:36:24
User opened query 'CDM-Coding: The trade name sudafed can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	01 Sep 2020 03:11:35
Data point term sent to Coder	System	22 Aug 2020 19:18:02
User entered 'sudafed'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'medical history: seasonal allergies'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered '60'	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'un UNK 2000'	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	22 Aug 2020 19:17:57
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 19:17:57

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Aug 2020 05:05:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 05:05:32
Data point term sent to Coder	System	22 Aug 2020 19:20:03
User entered 'guaifenesin'	Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'medical history: seasonal allergies'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '400'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	22 Aug 2020 19:19:14
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'un Jan 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 19:19:14

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:43
User closed query 'Per CDM: Please agree to add 'vaccine' to the medication name.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 06:25:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 14:00:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 14:00:54
Data point term sent to Coder	System	23 Apr 2021 21:17:35
Query 'Per CDM: Please agree to add 'vaccine' to the medication name.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:17:24
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:17:10
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:17:10
User entered 'MODERNA MRNA-1273 vaccine' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	23 Apr 2021 21:17:10
User opened query 'Per CDM: Please agree to add 'vaccine' to the medication name.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 18:44:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	09 Apr 2021 18:08:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:28:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:28:38
Data point term sent to Coder	System	07 Apr 2021 19:08:19
User entered 'moderna mRNA-1273'	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered 'prophylaxis against covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered '7 Jan 2021'	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
	(b) (4)	
User entered '7 Jan 2021'	Kelsey Kelley (b) (4)	07 Apr 2021 19:08:16
	(b) (4)	

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:08:42
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:55:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 19:08:16

US3032320

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:55:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	22 Aug 2020 17:51:42
	(b) (4)	

US3032320

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:55:41

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Dec 2020 16:22:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 16:22:00
User entered '21 Sep 2020' reason for change: Data Entry Error	Russell Herstein (b) (4)	01 Dec 2020 16:22:00
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 16:21:22
User entered empty.	Russell Herstein (b) (4)	01 Dec 2020 16:21:22

US3032320

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:55:41

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4)	02 Dec 2020 17:39:13
reason for change: Data Entry Error	Kelsey Kelley (b) (4)	02 Dec 2020 17:39:13
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4)	01 Dec 2020 16:23:36
reason for change: Data Entry Error	Russell Herstein (b) (4)	01 Dec 2020 16:23:36
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4)	01 Dec 2020 16:21:22
	Russell Herstein (b) (4)	01 Dec 2020 16:21:22
	(b) (4)	

US3032320

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:49:16
User closed query 'Per CDM: Please note that "Due to SARS-COV-2" is one of the options for dosing discontinuation from the dropdown list provided. Please update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 06:29:49
Query 'Per CDM: Please note that "Due to SARS-COV-2" is one of the options for dosing discontinuation from the dropdown list provided. Please update if appropriate.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 17:39:21
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 17:39:13
User opened query 'Per CDM: Please note that "Due to SARS-COV-2" is one of the options for dosing discontinuation from the dropdown list provided. Please update if appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:27:33
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:23:51
User entered 'sars-cov-2 infection' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 16:23:51
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	01 Dec 2020 16:23:36
User entered empty.	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 16:21:22

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered '7 Jan 2021'	Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	23 Apr 2021 19:37:27
User closed query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 08:35:27
Query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' answered with 'Per sponsor Subject was withdrawn from the study due to receiving a vaccination and was marked as a protocol deviation' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Apr 2021 20:04:48
User opened query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:48:58
User closed query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:48:58
Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'Updated per query' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:06:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:06:01
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	07 Apr 2021 19:06:01

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User opened query ' Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	07 Apr 2021 05:38:07
	Keith Vrbicky (b) (4) (b) (4)	04 Mar 2021 16:05:46
User entered 'Other (OTHER)'	Samantha Wieseler (b) (4) (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered 'Subject received vaccine through work.'	Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:55:41

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:05:46
User entered empty.	Samantha Wieseler (b) (4)	25 Feb 2021 23:48:52

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'USA-US032-2020-MRNA-1273-P301000004'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Keith'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Vrbicky'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 02:20:12
Reviewed for Safety.	System	18 Sep 2020 16:40:12
User entered 'US' (non-conformant).	(b) (4), (b) (6)	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '2'	(b) (4)	18 Sep 2020 16:40:24
User entered '1'	System	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'USA-US032-2020-MRNA-1273-P301000004'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Keith'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Vrbicky'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 02:20:12
Reviewed for Safety.	System	18 Sep 2020 16:40:12
User entered 'US' (non-conformant).	(b) (4), (b) (6)	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '2'	(b) (4)	18 Sep 2020 16:40:24
User entered '1'	System	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:55:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '16/Sep/2020 08:34'	(b) (4) System	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:55:41

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)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:40:12
User entered '1'		16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'USA-US032-2020-MRNA-1273-P301000004'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'No (N)'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Keith'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:34:28
User entered 'Vrbicky'	System	16 Sep 2020 12:29:38

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
Amendment Manager: Data point set to conformant.	(b) (4)	19 Sep 2020 02:20:12
Reviewed for Safety.	System	18 Sep 2020 16:40:12
User entered 'US' (non-conformant).	(b) (4), (b) (6)	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 21:55:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '2'	(b) (4)	18 Sep 2020 16:40:24
User entered '1'	System	16 Sep 2020 12:34:35

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:55:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered '18/Sep/2020 12:40'	(b) (4) System	18 Sep 2020 16:40:24

US3032320

Folder: SAE USA-US032-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:55:41

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)	26 Apr 2021 19:48:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 18:14:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:40:24