

US3032204 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:51:53

All time stamps listed in this document are displayed in GMT

US3032204

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:34:15

Generated On: 09 Jun 2021 14:51:53

Participant ID

US3032204

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

US3032204

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3032204

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
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

US3032204

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Date of Informed Consent (*dd MMM yyyy*) 14 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3032204

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Did the participant meet all eligibility criteria?

Yes

No

US3032204

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Were any significant conditions reported?

Yes

No

US3032204

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN JAN 2019
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)	17 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

US3032204

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	TYPE 1 DIABETIC
Start date (dd MMM yyyy)	UN UNK 1986
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)	17 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

US3032204

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	C 8-9 TAKEN OUT, REPLACED WITH A PLATE
Start date (dd MMM yyyy)	UN MAY 2019
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 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

US3032204

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	HEAD CONTUSION DUE TO FALL ON ICE
Start date (dd MMM yyyy)	UN MAR 2019
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 MAR 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAR 2019
Stop Year (derived)	2019

US3032204

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2017
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)	17 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

US3032204

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Condition	HEADACHES
Start date (dd MMM yyyy)	UN JAN 2019
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 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

US3032204

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:36:16

Generated On: 09 Jun 2021 14:51:53

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 14 AUG 2020

Time of assessment (*00:00-23:59*) 10:25 (24 HR)

Vital Signs Date and Time (derived) 14 AUG 2020 10:25

Height (*xxx.x*) 203.2 cm

Weight (*xxx.x*) 117.9 kg

BMI (*xxx.x*) 28.55396 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3032204

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

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

US3032204

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:34:16

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3032204

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

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)	False
Other	False
Specify	

US3032204

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 AUG 2020

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

Folder OID VISIT1

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 144011

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

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Height	ND - Not Done
Weight	ND - Not Done

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

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 (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:25 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:25
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:20
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3032204

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 11:49

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

US3032204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	14 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:15 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:15

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Collection date (<i>dd MMM yyyy</i>)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:04	14 AUG 2020 11:04
Nasopharyngeal Swab 2	No		

US3032204

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 14 AUG 2020 12:21
PC Open Date & Time 14 AUG 2020 12:09
PC Close Date & Time 14 AUG 2020 14:39

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 98.9 °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 14 AUG 2020 15:41
PC Open Date & Time 14 AUG 2020 15:34
PC Close Date & Time 15 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 12:37
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 13:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 AUG 2020 16:15
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 17:06
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 AUG 2020 16:29
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 20 AUG 2020 18:19

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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	14 AUG 2020 12:21
PC Open Date & Time	14 AUG 2020 12:09
PC Close Date & Time	14 AUG 2020 14:39

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

14 AUG 2020 15:42

PC Open Date & Time

14 AUG 2020 15:34

PC Close Date & Time

15 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 AUG 2020 12:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 AUG 2020 13:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 AUG 2020 16:15

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 AUG 2020 17:07

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 AUG 2020 16:30

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 AUG 2020 18:20

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

No

Yes

PC Time stamp	14 AUG 2020 12:22
PC Open Date & Time	14 AUG 2020 12:09
PC Close Date & Time	14 AUG 2020 14:39

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

No

Yes

PC Time stamp	14 AUG 2020 15:42
PC Open Date & Time	14 AUG 2020 15:34
PC Close Date & Time	15 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 12:38
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 13:44
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 16:16
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

Yes

PC Time stamp	18 AUG 2020 17:07
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	19 AUG 2020 16:30
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 18:20
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3032204

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032204

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:34:57

Generated On: 09 Jun 2021 14:51:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:34:57

Generated On: 09 Jun 2021 14:51:53

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 (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:27 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 16:27
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:34:57

Generated On: 09 Jun 2021 14:51:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	18:20 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 18:20
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3032204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:34:57

Generated On: 09 Jun 2021 14:51:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 17:46 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 17:46

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

US3032204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 SEP 2020

Collection time (*00:00-23:59*) 16:53 (24 HR)

Collection date and time (derived) 14 SEP 2020 16:53

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Collection date (<i>dd MMM yyyy</i>)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:42	14 SEP 2020 16:42
Nasopharyngeal Swab 2	No		

US3032204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 97.5 °F

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

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

PC Time Stamp 14 SEP 2020 18:20

PC Open Date & Time 14 SEP 2020 18:06

PC Close Date & Time 14 SEP 2020 20:36

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp 14 SEP 2020 21:34
PC Open Date & Time 14 SEP 2020 21:31
PC Close Date & Time 15 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 16:13
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 16:09
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 17 SEP 2020 16:25

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 SEP 2020 17:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 21:29
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 21:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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	14 SEP 2020 18:21
PC Open Date & Time	14 SEP 2020 18:06
PC Close Date & Time	14 SEP 2020 20:36

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

14 SEP 2020 21:36

PC Open Date & Time

14 SEP 2020 21:31

PC Close Date & Time

15 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	15 SEP 2020 16:14
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	16 SEP 2020 16:09
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 16:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 SEP 2020 17:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 SEP 2020 21:29

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 SEP 2020 21:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

No

Yes

PC Time stamp	14 SEP 2020 18:22
PC Open Date & Time	14 SEP 2020 18:06
PC Close Date & Time	14 SEP 2020 20:36

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

No

Yes

PC Time stamp	14 SEP 2020 21:37
PC Open Date & Time	14 SEP 2020 21:31
PC Close Date & Time	15 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 16:14
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 16:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 16:26
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 17:09
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 21:30
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 21:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3032204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032204

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:36:15

Generated On: 09 Jun 2021 14:51:53

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

US3032204

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:36:15

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:36:15

Generated On: 09 Jun 2021 14:51:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3032204

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:36:15

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 OCT 2020

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

Folder OID VISIT3

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:26 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 16:26
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3032204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 OCT 2020

Collection time (*00:00-23:59*) 16:34 (24 HR)

Collection date and time (derived) 12 OCT 2020 16:34

US3032204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Oct 2020 13:55:23

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 15 OCT 2020 19:09:12

Patient Cloud Open Date & Time 14 OCT 2020 00:01

Patient Cloud Close Date & Time 18 OCT 2020 23:59

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22 OCT 2020 21:49:31

Patient Cloud Open Date & Time 21 OCT 2020 00:01

Patient Cloud Close Date & Time 25 OCT 2020 23:59

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 29 OCT 2020 19:27:29

Patient Cloud Open Date & Time 28 OCT 2020 00:01

Patient Cloud Close Date & Time 01 NOV 2020 23:59

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 type="radio"/> Yes <input checked="" 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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="checkbox"/>
Date and time of submission	12 NOV 2020 15:52:31
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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 type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this 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 type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3032204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 21:37:40

Generated On: 09 Jun 2021 14:51:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3032204

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:29:25

Generated On: 09 Jun 2021 14:51:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Nov 2020 20:28:46

Generated On: 09 Jun 2021 14:51:53

Date of Contact	11 NOV 2020
Time of Contact	07:00
Date and Time of Contact (derived)	11 NOV 2020 07:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	37.0 C
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

131 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 12 NOV 2020

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 98.6 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

135 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.0 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

139 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 14 NOV 2020

Assessment Not Done False

O2 Saturation 87 %

O2 Saturation Units %

Temperature 99.0 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input checked="" type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input checked="" type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

143 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	91 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

147 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.3 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

151 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 09 NOV 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

None	<input type="checkbox"/>
Mild	<input checked="" type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Cough

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Shortness of Breath

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

Difficulty Breathing

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

155 of 1832

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 08 Dec 2020 19:48:07

Generated On: 09 Jun 2021 14:51:53

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Nov 2020 16:29:57

Generated On: 09 Jun 2021 14:51:53

Date of Visit 11 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 11 NOV 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:46

Generated On: 09 Jun 2021 14:51:53

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____
End Date _____
Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____
End Date _____
Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ \leq 93% on room air at sea level? Yes
No

If Yes, provide:

Start Date 14 NOV 2020
End Date 16 NOV 2020
Oxygen Saturation 87 %

Did the subject have PaO₂/FIO₂ Ratio $<$ 300 mm Hg? Yes
No

If Yes, provide:

Start Date _____
End Date _____
PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:46

Generated On: 09 Jun 2021 14:51:53

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes
No

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes
No

Start Date _____

End Date _____

Mechanical Ventilation? Yes
No

Start Date _____

End Date _____

ECMO? Yes
No

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes
No

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes
No

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes
No

Start Date _____

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:46

Generated On: 09 Jun 2021 14:51:53

Hepatic Dysfunction? Yes
No

Start Date _____

Neurologic Dysfunction? Yes
No

Start Date _____

Evidence of Pneumonia:

Clinical Evidence Yes
No

Date of Assessment _____

Radiographical Evidence Yes
No

Date of Assessment _____

Admission to an intensive care unit due to SARS-CoV-2 Yes
No

Start Date _____

End Date _____

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

[Generate Next COVID-19 Assessment](#)

Yes

No

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 NOV 2020
Day 5	Yes	15 NOV 2020
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3032204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:25 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 15:25
Height (<i>xxx.x</i>)	203.2 cm
Weight (<i>xxx.x</i>)	117.9 kg
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3032204

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3032204

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

11 NOV 2020

US3032204

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Nov 2020 15:51:38

Generated On: 09 Jun 2021 14:51:53

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

AEID USA-US032-2020-MRNA-1273-P30
1000012

Adverse event SYMPTOMATIC COVID-19

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 9 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 16 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death True

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input checked="" type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	SITE WAS MADE AWARE OF PATIENT BEING DECEASED BY LOCAL NEWSPAPER OBITUARY
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

170 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

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

Yes

No

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication TOPROL

Prophylaxis Yes
No

Indication MEDICAL HISTORY:
HEADACHES

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) UN MAY 2019

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ARMOUR THYROID

Prophylaxis Yes
No

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

Dose per administration 240

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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 2019
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"/>

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ATORVASTATIN

Prophylaxis Yes
No

Indication MEDICAL HISTORY:
HYPERCHOLESTEROLEMIA

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

176 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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 JAN 2019

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication TRESIBA

Prophylaxis Yes
No

Indication MEDICAL HISTORY: TYPE 1
DIABETES

Dose per administration 28

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNITS

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)

178 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" 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 MAR 2019
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"/>

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication FIASP FLEX TOUCH

Prophylaxis Yes
No

Indication MEDICAL HISTORY: DIABETES
TYPE 1

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNIT PER CARB (SLIDING
SCALE)

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)

180 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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 JUN 2019

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ARMOUR THYROID

Prophylaxis Yes
No

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

Dose per administration 180

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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 NOV 2019

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes
No

Indication PROPHYLAXIS FOR SEASONAL
INFLUENZA

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)

184 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" 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) 30 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

186 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

	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*) _____ 09 NOV 2020

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

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

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ONDANSETRON

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 8

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication AZITHROMYCIN

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

190 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 24

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 11 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 16

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

196 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 12 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 12 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 12

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

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 13 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 13 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 8

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

200 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 14 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 15 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication ALBUTEROL NEBULIZER

Prophylaxis Yes
No

Indication COVID-LIKE ILLNESS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify TREATMENT

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

204 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 14 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 16 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Name of Medication AZITHROMYACIN

Prophylaxis Yes
No

Indication COVID LIKE ILLNESS

Dose per administration 250

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

206 of 1832

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

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*) 11 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3032204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 17:34:16

Generated On: 09 Jun 2021 14:51:53

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

Date of study discontinuation/completion (*dd MMM yyyy*) 16 NOV 2020

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Other

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

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify _____

Date of death (*dd MMM yyyy*) 16 NOV 2020

Was autopsy performed?

Yes

No

Unknown

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P30 1000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	18/NOV/2020 13:46
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

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P30 1000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:28
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

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	03/FEB/2021 16:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 06 Apr 2021 15:38:49

Generated On: 09 Jun 2021 14:51:53

SAEID	USA-US032-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 09:51
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.	<input checked="" type="checkbox"/> True

Audit

US3032204 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032204

Form: Participant Creation

Generated On: 09 Jun 2021 14:51:53

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	14 Apr 2021 14:56:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'US3032204'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:55

US3032204

Form: Participant Creation

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:08:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:02
	(b) (4)	

US3032204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:08:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:56

US3032204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:08:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:02

US3032204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'SCRN'	System	14 Aug 2020 17:02:02

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:57

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '54'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'YEARS'	System	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '54'	System	14 Aug 2020 17:02:29

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Male (M)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '1'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15

US3032204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:53

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:09:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:15
	(b) (4)	

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:29

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Aug 2020'	System	14 Aug 2020 17:02:29

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2020'	System	14 Aug 2020 17:02:29

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Amendment 2 (2)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:29
	(b) (4)	

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:29
	(b) (4)	

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:29
	(b) (4)	

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:29
	(b) (4)	

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:02:29

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:56

US3032204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 17:02:34

US3032204

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:02:34
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:51:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:09:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:42

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 15 Aug 2020 00:12:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	(b) (4) 15 Aug 2020 00:12:28
Data point term sent to Coder	System	14 Aug 2020 20:24:16
User entered 'hypercholesterolemia'	Kelsey Kelley (b) (4) (b) (4)	(b) (4) 14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'UN Jan 2019' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 19:11:31
User entered 'un Feb 2020'	Linden DeBoer (b) (4)	14 Aug 2020 20:23:59
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	04 Dec 2020 22:29:45
DataPoint Un-verified.	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:45
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	04 Dec 2020 22:29:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	04 Dec 2020 22:29:45
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	04 Dec 2020 22:29:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:23:59
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:41
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:41
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Aug 2020 20:23:59
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Jan 2019'	System	30 Sep 2020 19:11:31
User entered 'Feb 2020'	System	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	30 Sep 2020 19:11:31
User entered '2020'	System	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Nov 2020'	System	04 Dec 2020 22:29:41
User entered empty.	System	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2020'	System	04 Dec 2020 22:29:41
User entered empty.	System	14 Aug 2020 20:23:59

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review Con Meds #4 and #5 if they were given for this medical condition. If yes, please update the indications in Con Meds eCRF to reflect a match with this medical history condition as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 08:29:34
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review Con Meds #4 and #5 if they were given for this medical condition. If yes, please update the indications in Con Meds eCRF to reflect a match with this medical history condition as appropriate.' answered with 'Con meds updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:30:25
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review Con Meds #4 and #5 if they were given for this medical condition. If yes, please update the indications in Con Meds eCRF to reflect a match with this medical history condition as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 14:26:01
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 05:59:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 05:59:41
Data point term sent to Coder	System	14 Aug 2020 20:24:17
User entered 'type 1 diabetic'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'un UNK 1986'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	14 Aug 2020 20:24:15
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:55
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Aug 2020 20:24:15
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Jan 1986'	System	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1986'	System	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Nov 2020'	System	04 Dec 2020 22:29:55
User entered empty.	System	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2020'	System	04 Dec 2020 22:29:55
User entered empty.	System	14 Aug 2020 20:24:15

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition or procedure. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 08:32:54
Query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition or procedure. Please reconcile with applicable eCRF as appropriate.' answered with 'subject fell on ice. this information is in MH ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	29 Sep 2020 17:50:38
User opened query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition or procedure. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 14:27:51
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:22:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:22:10
Data point term sent to Coder System	System	14 Aug 2020 20:25:21
User entered 'c 8-9 taken out, replaced with a plate'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'un May 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4) System	18 Aug 2020 13:56:57
User entered 'UN May 2019' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:56:57
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	14 Aug 2020 20:24:59
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'May 2019'	System	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'May 2019'	System	18 Aug 2020 13:56:57
User entered 'Jan 2019'	System	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	14 Aug 2020 20:24:59

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:14:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 12:14:07
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 07:35:08
Data point term sent to Coder	System	30 Sep 2020 18:31:22
Query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition. Please reconcile with applicable eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Russell Herstein (b) (4)	30 Sep 2020 18:30:59
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' (Site from System).	System	30 Sep 2020 18:30:51
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' answered with 'UPDATED' (Site from System).	Russell Herstein (b) (4)	30 Sep 2020 18:30:51
User entered 'HEAD CONTUSION DUE TO FALL ON ICE' reason for change: Data Entry Error	Russell Herstein (b) (4)	30 Sep 2020 18:30:44
User opened query 'Per DM CLR: Please verify MH term and add details to reflect a medical condition. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 14:27:07
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' (Site from System).	Coder Import (b) (4)	18 Aug 2020 17:27:04
Data point term sent to Coder	System	14 Aug 2020 20:26:22
User entered 'Fell on ice, hit head'	Kelsey Kelley (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'un Mar 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'un Mar 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Mar 2019'	System	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Mar 2019'	System	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	14 Aug 2020 20:25:28

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 22:30:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Dec 2020 22:30:06
Data point term sent to Coder DataPoint Un-verified.	System	04 Dec 2020 22:29:35
Coding entries removed.	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:06
Signature has been broken.	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:06
User entered 'HYPOTHYROIDism' reason for change: Data Entry Error DataPoint Verified.	Samantha Wieseler (b) (4)	04 Dec 2020 22:29:06
User signature succeeded.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:12:36
Data point term sent to Coder User entered 'hypothyroid'	Coder Import (b) (4)	15 Aug 2020 00:12:36
	System	14 Aug 2020 20:26:23
	Kelsey Kelley (b) (4)	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	14 Aug 2020 20:25:42
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:30:15
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Aug 2020 20:25:42
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Jan 2017'	System	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2017'	System	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Nov 2020'	System	04 Dec 2020 22:30:15
User entered empty.	System	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2020'	System	04 Dec 2020 22:30:15
User entered empty.	System	14 Aug 2020 20:25:42

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 18:25:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:25:54
Data point term sent to Coder	System	30 Sep 2020 18:25:11
User entered 'HEADACHES'	Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:58:09
User entered 'UN Jan 2019' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:26:48
User entered 'UN May 2019'	Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	30 Sep 2020 18:26:58
User entered 'No (N)' reason for change: Data Entry Error	Russell Herstein (b) (4)	30 Sep 2020 18:26:58
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	30 Sep 2020 18:24:58
User entered 'Yes (Y)'	Russell Herstein (b) (4)	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'UN May 2019' reason for change:	(b) (4)	
Data Entry Error	Russell Herstein (b) (4)	30 Sep 2020 18:26:48
User entered 'UN UNK 2020'	(b) (4)	
	Russell Herstein (b) (4)	30 Sep 2020 18:24:58
	(b) (4)	

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:10:43
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'Jan 2019'	System	30 Sep 2020 18:26:48
User entered 'May 2019'	System	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'May 2019'	System	30 Sep 2020 18:26:48
User entered 'Jan 2020'	System	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '2019'	System	30 Sep 2020 18:26:48
User entered '2020'	System	30 Sep 2020 18:24:58

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '10:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '203.2' cm	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:02:34

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '117.9' kg	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:02:34

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Amendment Manager: User entered '28.55396'	System	16 Sep 2020 23:57:18
User entered '28.6'	System	14 Aug 2020 20:21:48
DataPoint set to visible.	System	14 Aug 2020 17:02:34

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'kg/m2'	System	14 Aug 2020 20:21:48
DataPoint set to visible.	System	14 Aug 2020 17:02:34

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
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 06:52:41
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 14:35:43
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:35:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:35:38
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 11:33:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
User entered '36.8' C	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
	(b) (4)	

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '75'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
	(b) (4)	

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
	(b) (4)	

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (.xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
	(b) (4)	
User entered '120'	Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
	(b) (4)	

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:13:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	07 Oct 2020 14:35:38
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '82'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:21:48
	(b) (4)	

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:21:48

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:31
Query 'Per the source the physical exam was completed please update ' canceled (Site from CRA)		02 Dec 2020 16:15:07
User opened query 'Per the source the physical exam was completed please update ' (Site from CRA).		02 Dec 2020 16:14:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 21:07:31
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	14 Aug 2020 20:21:54
	(b) (4)	

US3032204

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	15 Sep 2020 21:07:31
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 21:07:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:03:49
User entered '14 Aug 2020'	Kelsey Kelley (b) (4)	14 Aug 2020 20:21:54

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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)	6 Apr 2021 19:47:58
DataPoint Verified.		2 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:20:57

US3032204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:10

US3032204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:10

US3032204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:10

US3032204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'VISIT1'	System	14 Aug 2020 20:20:10

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:19:41

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:33:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:33:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:19:41
User entered '144011' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:19:41

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:19:41

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:01

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:01

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:01

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:01

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:20:01

US3032204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:16:01
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).		02 Nov 2020 07:50:03
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 14:02:25
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:36:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:25:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:18:16

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
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)	13 Oct 2020 04:52:34
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 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
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)	12 Oct 2020 11:56:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
User entered '203.2' cm	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '117.9' kg	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:22:36
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
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)	13 Oct 2020 04:52:34
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 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
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)	12 Oct 2020 11:56:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
User entered '203.2' cm	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
	(b) (4)	
User entered '117.9' kg	Kelsey Kelley (b) (4)	14 Aug 2020 20:22:36
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '10:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '75'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '120'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
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)	13 Oct 2020 04:52:34
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 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:13
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:23:09
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)	12 Oct 2020 11:56:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
User entered '203.2' cm	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:22:36

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:23:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '117.9' kg	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:22:36
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 04:42:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 20:23:25
User entered '12:20'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 12:20'	System	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '68'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '120'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '80'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	14 Aug 2020 20:23:25

US3032204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:19:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:52

US3032204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:19:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:25:52

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:03:03
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:03:03
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '11:49'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 11:49'	System	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4)	14 Aug 2020 17:03:03
	(b) (4)	

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:05
User entered 'ONCE'	System	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 17:03:03

US3032204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:31

US3032204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:20:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:26:31

US3032204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '11:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:31

US3032204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 11:15'	System	14 Aug 2020 20:26:31

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '11:04'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Aug 2020 11:04'	System	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	14 Aug 2020 20:26:14

US3032204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:20:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:26:21

US3032204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:26:21

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:20:10', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08b97936-fee0-40ea-a099-c1b73e6a7437'	System	14 Aug 2020 17:21:18
User entered 'Yes (Y)'	System	14 Aug 2020 17:21:18

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:20:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08b97936-fee0-40ea-a099-c1b73e6a7437'	System	14 Aug 2020 17:21:18
User entered '98.0'	System	14 Aug 2020 17:21:18

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:04', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08b97936-fee0-40ea-a099-c1b73e6a7437'	System	14 Aug 2020 17:21:18
User entered 'No (N)'	System	14 Aug 2020 17:21:18

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:13', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08b97936-fee0-40ea-a099-c1b73e6a7437'	System	14 Aug 2020 17:21:18
User entered '14 Aug 2020 12:21'	System	14 Aug 2020 17:21:18

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 12:09'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 14:39'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:10', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd48d1280-96e5-4b81-8f76-4c3aeedf4023'	System	14 Aug 2020 20:41:57
User entered 'Yes (Y)'	System	14 Aug 2020 20:41:57

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:27', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd48d1280-96e5-4b81-8f76-4c3aeedf4023'	System	14 Aug 2020 20:41:57
User entered '98.9'	System	14 Aug 2020 20:41:57

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:33', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd48d1280-96e5-4b81-8f76-4c3aeedf4023'	System	14 Aug 2020 20:41:57
User entered 'No (N)'	System	14 Aug 2020 20:41:57

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:42', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd48d1280-96e5-4b81-8f76-4c3aeedf4023'	System	14 Aug 2020 20:41:57
User entered '14 Aug 2020 15:41'	System	14 Aug 2020 20:41:57

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 15:34'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 2'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:36:38', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'eb8f233f-1e40-4395-9ae0-4471d194c2f4'	System	15 Aug 2020 17:37:04
User entered 'Yes (Y)'	System	15 Aug 2020 17:37:04

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:36:50', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'eb8f233f-1e40-4395-9ae0-4471d194c2f4'	System	15 Aug 2020 17:37:04
User entered '98.1'	System	15 Aug 2020 17:37:04

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:36:56', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'eb8f233f-1e40-4395-9ae0-4471d194c2f4'	System	15 Aug 2020 17:37:04
User entered 'No (N)'	System	15 Aug 2020 17:37:04

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'eb8f233f-1e40-4395-9ae0-4471d194c2f4'	System	15 Aug 2020 17:37:04
User entered '15 Aug 2020 12:37'	System	15 Aug 2020 17:37:04

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 3'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:41:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '97c8998c-b459-4a03-8af5-ec88442f0314'	System	16 Aug 2020 18:42:32
User entered 'Yes (Y)'	System	16 Aug 2020 18:42:32

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:42:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '97c8998c-b459-4a03-8af5-ec88442f0314'	System	16 Aug 2020 18:42:32
User entered '98.1'	System	16 Aug 2020 18:42:32

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:42:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '97c8998c-b459-4a03-8af5-ec88442f0314'	System	16 Aug 2020 18:42:32
User entered 'No (N)'	System	16 Aug 2020 18:42:32

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:42:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '97c8998c-b459-4a03-8af5-ec88442f0314'	System	16 Aug 2020 18:42:32
User entered '16 Aug 2020 13:42'	System	16 Aug 2020 18:42:32

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 4'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:13:52', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'acdde46e-6810-4ac3-a643-0c5ba7d599dd'	System	17 Aug 2020 21:15:16
User entered 'Yes (Y)'	System	17 Aug 2020 21:15:16

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:14:59', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'acdde46e-6810-4ac3-a643-0c5ba7d599dd'	System	17 Aug 2020 21:15:16
User entered '96.9'	System	17 Aug 2020 21:15:16

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:03', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'acdde46e-6810-4ac3-a643-0c5ba7d599dd'	System	17 Aug 2020 21:15:16
User entered 'No (N)'	System	17 Aug 2020 21:15:16

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'acdde46e-6810-4ac3-a643-0c5ba7d599dd'	System	17 Aug 2020 21:15:16
User entered '17 Aug 2020 16:15'	System	17 Aug 2020 21:15:16

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 5'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:05:36', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aea2e314-1f97-4d42-bc1c-eb9a3ad0f7d0'	System	18 Aug 2020 22:06:40
User entered 'Yes (Y)'	System	18 Aug 2020 22:06:40

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aea2e314-1f97-4d42-bc1c-eb9a3ad0f7d0'	System	18 Aug 2020 22:06:40
User entered '98.1'	System	18 Aug 2020 22:06:40

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:32', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aea2e314-1f97-4d42-bc1c-eb9a3ad0f7d0'	System	18 Aug 2020 22:06:40
User entered 'No (N)'	System	18 Aug 2020 22:06:40

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:36', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aea2e314-1f97-4d42-bc1c-eb9a3ad0f7d0'	System	18 Aug 2020 22:06:40
User entered '18 Aug 2020 17:06'	System	18 Aug 2020 22:06:40

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 6'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6c495cf-ee30-4b6e-88f1-01469f38d43b'	System	19 Aug 2020 21:29:42
User entered 'Yes (Y)'	System	19 Aug 2020 21:29:42

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6c495cf-ee30-4b6e-88f1-01469f38d43b'	System	19 Aug 2020 21:29:42
User entered '97.4'	System	19 Aug 2020 21:29:42

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:36', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6c495cf-ee30-4b6e-88f1-01469f38d43b'	System	19 Aug 2020 21:29:42
User entered 'No (N)'	System	19 Aug 2020 21:29:42

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:39', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6c495cf-ee30-4b6e-88f1-01469f38d43b'	System	19 Aug 2020 21:29:42
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 21:29:42

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 7'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:19:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db16fac8-12cf-423d-8fcc-23972c572dfc'	System	20 Aug 2020 23:19:56
User entered 'Yes (Y)'	System	20 Aug 2020 23:19:56

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:19:40', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db16fac8-12cf-423d-8fcc-23972c572dfc'	System	20 Aug 2020 23:19:56
User entered '97.9'	System	20 Aug 2020 23:19:56

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:19:44', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db16fac8-12cf-423d-8fcc-23972c572dfc'	System	20 Aug 2020 23:19:56
User entered 'No (N)'	System	20 Aug 2020 23:19:56

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:19:53', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db16fac8-12cf-423d-8fcc-23972c572dfc'	System	20 Aug 2020 23:19:56
User entered '20 Aug 2020 18:19'	System	20 Aug 2020 23:19:56

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6d209e9-2c2e-4c7a-86c7-b0e2a9ec46de'	System	14 Aug 2020 17:21:44
User entered 'None (1)'	System	14 Aug 2020 17:21:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:25', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6d209e9-2c2e-4c7a-86c7-b0e2a9ec46de'	System	14 Aug 2020 17:21:44
User entered 'No (N)'	System	14 Aug 2020 17:21:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6d209e9-2c2e-4c7a-86c7-b0e2a9ec46de'	System	14 Aug 2020 17:21:44
User entered 'No (N)'	System	14 Aug 2020 17:21:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6d209e9-2c2e-4c7a-86c7-b0e2a9ec46de'	System	14 Aug 2020 17:21:44
User entered 'None (1)'	System	14 Aug 2020 17:21:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:40', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a6d209e9-2c2e-4c7a-86c7-b0e2a9ec46de'	System	14 Aug 2020 17:21:44
User entered '14 Aug 2020 12:21'	System	14 Aug 2020 17:21:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 12:09'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 14:39'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1ab97628-385f-420c-b27e-e4a7d33b1abf'	System	14 Aug 2020 20:42:17
User entered 'None (1)'	System	14 Aug 2020 20:42:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:41:59', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1ab97628-385f-420c-b27e-e4a7d33b1abf'	System	14 Aug 2020 20:42:17
User entered 'No (N)'	System	14 Aug 2020 20:42:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1ab97628-385f-420c-b27e-e4a7d33b1abf'	System	14 Aug 2020 20:42:17
User entered 'No (N)'	System	14 Aug 2020 20:42:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:08', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1ab97628-385f-420c-b27e-e4a7d33b1abf'	System	14 Aug 2020 20:42:17
User entered 'None (1)'	System	14 Aug 2020 20:42:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1ab97628-385f-420c-b27e-e4a7d33b1abf'	System	14 Aug 2020 20:42:17
User entered '14 Aug 2020 15:42'	System	14 Aug 2020 20:42:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 15:34'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 2'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '824bb0cf-cbbe-49a9-a6c3-890bd5a3ff13'	System	15 Aug 2020 17:37:54
User entered 'None (1)'	System	15 Aug 2020 17:37:54

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '824bb0cf-cbbe-49a9-a6c3-890bd5a3ff13'	System	15 Aug 2020 17:37:54
User entered 'No (N)'	System	15 Aug 2020 17:37:54

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:38', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '824bb0cf-cbbe-49a9-a6c3-890bd5a3ff13'	System	15 Aug 2020 17:37:54
User entered 'No (N)'	System	15 Aug 2020 17:37:54

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '824bb0cf-cbbe-49a9-a6c3-890bd5a3ff13'	System	15 Aug 2020 17:37:54
User entered 'None (1)'	System	15 Aug 2020 17:37:54

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:37:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '824bb0cf-cbbe-49a9-a6c3-890bd5a3ff13'	System	15 Aug 2020 17:37:54
User entered '15 Aug 2020 12:37'	System	15 Aug 2020 17:37:54

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 3'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:42:55', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1fcfc0df-9ed7-4719-a5ae-41e874855935'	System	16 Aug 2020 18:43:28
User entered 'None (1)'	System	16 Aug 2020 18:43:28

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:04', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1fcfc0df-9ed7-4719-a5ae-41e874855935'	System	16 Aug 2020 18:43:28
User entered 'No (N)'	System	16 Aug 2020 18:43:28

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:10', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1fcfc0df-9ed7-4719-a5ae-41e874855935'	System	16 Aug 2020 18:43:28
User entered 'No (N)'	System	16 Aug 2020 18:43:28

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:17', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1fcfc0df-9ed7-4719-a5ae-41e874855935'	System	16 Aug 2020 18:43:28
User entered 'None (1)'	System	16 Aug 2020 18:43:28

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '1fcfc0df-9ed7-4719-a5ae-41e874855935'	System	16 Aug 2020 18:43:28
User entered '16 Aug 2020 13:43'	System	16 Aug 2020 18:43:28

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 4'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:16', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '21cb1a4c-9adf-4b56-a12a-218dce659f26'	System	17 Aug 2020 21:15:44
User entered 'None (1)'	System	17 Aug 2020 21:15:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '21cb1a4c-9adf-4b56-a12a-218dce659f26'	System	17 Aug 2020 21:15:44
User entered 'No (N)'	System	17 Aug 2020 21:15:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '21cb1a4c-9adf-4b56-a12a-218dce659f26'	System	17 Aug 2020 21:15:44
User entered 'No (N)'	System	17 Aug 2020 21:15:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:39', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '21cb1a4c-9adf-4b56-a12a-218dce659f26'	System	17 Aug 2020 21:15:44
User entered 'None (1)'	System	17 Aug 2020 21:15:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:43', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '21cb1a4c-9adf-4b56-a12a-218dce659f26'	System	17 Aug 2020 21:15:44
User entered '17 Aug 2020 16:15'	System	17 Aug 2020 21:15:44

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 5'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:47', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '5df3fe70-659e-4de6-8323-4c8ed9a55ee7'	System	18 Aug 2020 22:07:09
User entered 'None (1)'	System	18 Aug 2020 22:07:09

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:52', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '5df3fe70-659e-4de6-8323-4c8ed9a55ee7'	System	18 Aug 2020 22:07:09
User entered 'No (N)'	System	18 Aug 2020 22:07:09

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:06:57', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '5df3fe70-659e-4de6-8323-4c8ed9a55ee7'	System	18 Aug 2020 22:07:09
User entered 'No (N)'	System	18 Aug 2020 22:07:09

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '5df3fe70-659e-4de6-8323-4c8ed9a55ee7'	System	18 Aug 2020 22:07:09
User entered 'None (1)'	System	18 Aug 2020 22:07:09

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '5df3fe70-659e-4de6-8323-4c8ed9a55ee7'	System	18 Aug 2020 22:07:09
User entered '18 Aug 2020 17:07'	System	18 Aug 2020 22:07:09

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 6'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '0691c0af-fabd-4816-9fb4-71412aa4a6f5'	System	19 Aug 2020 21:30:10
User entered 'None (1)'	System	19 Aug 2020 21:30:10

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:54', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '0691c0af-fabd-4816-9fb4-71412aa4a6f5'	System	19 Aug 2020 21:30:10
User entered 'No (N)'	System	19 Aug 2020 21:30:10

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:29:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '0691c0af-fabd-4816-9fb4-71412aa4a6f5'	System	19 Aug 2020 21:30:10
User entered 'No (N)'	System	19 Aug 2020 21:30:10

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '0691c0af-fabd-4816-9fb4-71412aa4a6f5'	System	19 Aug 2020 21:30:10
User entered 'None (1)'	System	19 Aug 2020 21:30:10

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '0691c0af-fabd-4816-9fb4-71412aa4a6f5'	System	19 Aug 2020 21:30:10
User entered '19 Aug 2020 16:30'	System	19 Aug 2020 21:30:10

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 7'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:19:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a8fffaec-4ccb-4f2d-9f3c-65b4ba8c1e52'	System	20 Aug 2020 23:20:17
User entered 'None (1)'	System	20 Aug 2020 23:20:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:03', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a8fffaec-4ccb-4f2d-9f3c-65b4ba8c1e52'	System	20 Aug 2020 23:20:17
User entered 'No (N)'	System	20 Aug 2020 23:20:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a8fffaec-4ccb-4f2d-9f3c-65b4ba8c1e52'	System	20 Aug 2020 23:20:17
User entered 'No (N)'	System	20 Aug 2020 23:20:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a8fffaec-4ccb-4f2d-9f3c-65b4ba8c1e52'	System	20 Aug 2020 23:20:17
User entered 'None (1)'	System	20 Aug 2020 23:20:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:13', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a8fffaec-4ccb-4f2d-9f3c-65b4ba8c1e52'	System	20 Aug 2020 23:20:17
User entered '20 Aug 2020 18:20'	System	20 Aug 2020 23:20:17

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:54', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:21:57', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:08', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'None (0)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:27', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered 'No (N)'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T12:22:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'ede3cea4-e88e-487e-b111-a37274946933'	System	14 Aug 2020 17:22:37
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 17:22:37

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 12:09'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 14:39'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'None (0)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:52', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered 'No (N)'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-14T15:42:57', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '79bdad15-f7cb-4101-9e40-e62370decdded'	System	14 Aug 2020 20:43:03
User entered '14 Aug 2020 15:42'	System	14 Aug 2020 20:43:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Aug 2020 15:34'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 2'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:00', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:19', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'None (0)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:46', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered 'No (N)'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-15T12:38:56', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '17397867-b473-4968-9e73-18c985a5f790'	System	15 Aug 2020 17:39:00
User entered '15 Aug 2020 12:38'	System	15 Aug 2020 17:39:00

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 3'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:43:42', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:25', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'None (0)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:38', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered 'No (N)'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-16T13:44:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '3ca88aaa-5ebd-4efe-9395-b807c552b41e'	System	16 Aug 2020 18:44:48
User entered '16 Aug 2020 13:44'	System	16 Aug 2020 18:44:48

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 4'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:48', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:55', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:15:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:16:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:16:08', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'None (0)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:16:13', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered 'No (N)'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-17T16:16:16', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b6256d92-6d26-4088-9eb9-9d8f512fce00'	System	17 Aug 2020 21:16:21
User entered '17 Aug 2020 16:16'	System	17 Aug 2020 21:16:21

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 5'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:17', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:22', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:32', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'None (0)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:38', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c'	System	18 Aug 2020 22:07:45
User entered 'No (N)'	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-18T17:07:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '7927ec26-b3d0-45f8-ba26-8f45fee2bc1c' User entered '18 Aug 2020 17:07'	System	18 Aug 2020 22:07:45
	System	18 Aug 2020 22:07:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 6'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:12', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:17', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'None (0)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:50', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered 'No (N)'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-19T16:30:53', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'fe57b880-76a4-4f31-9e7e-6116d1551f68'	System	19 Aug 2020 21:30:58
User entered '19 Aug 2020 16:30'	System	19 Aug 2020 21:30:58

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 7'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'None (0)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'None (0)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'None (0)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:27', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f' User entered 'None (0)'	System	20 Aug 2020 23:20:45
	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:30', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'None (0)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'None (0)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:39', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered 'No (N)'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-08-20T18:20:43', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'a20f58d6-d2ad-4b1a-9e62-e227cc410f5f'	System	20 Aug 2020 23:20:45
User entered '20 Aug 2020 18:20'	System	20 Aug 2020 23:20:45

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:03:03

US3032204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:22:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 22:19:26

US3032204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:22:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '24 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 22:19:26

US3032204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:22:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 22:19:26

US3032204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:22:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 22:19:26

US3032204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:22:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 22:19:29

US3032204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'I'	System	25 Aug 2020 22:19:29

US3032204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:23:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 13:58:39

US3032204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:23:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '31 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 13:58:39

US3032204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:23:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 13:58:39

US3032204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:23:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 13:58:39

US3032204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:23:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	01 Sep 2020 13:58:42

US3032204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'I'	System	01 Sep 2020 13:58:42

US3032204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Sep 2020 22:04:36

US3032204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '04 Sep 2020'	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:04:36
	(b) (4)	

US3032204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Sep 2020 22:04:36

US3032204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	08 Sep 2020 22:04:36
	(b) (4)	

US3032204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Sep 2020 22:04:39

US3032204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	08 Sep 2020 22:04:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:24:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 22:03:49
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 22:03:49
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:24:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 22:03:49

US3032204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'VISIT2'	System	14 Sep 2020 22:03:49

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:47:58
DataPoint Verified.		2 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '16:27'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Sep 2020 16:27'	System	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '73'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '139'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '78'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	15 Sep 2020 00:43:08

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '18:20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Sep 2020 18:20'	System	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '36.4' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '58'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '126'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:25:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '72' reason for change: Data Entry Error	System	15 Sep 2020 00:43:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	15 Sep 2020 00:43:44
User entered '72.' (non-conformant).	(b) (4)	
	System	15 Sep 2020 00:43:39
	Kelsey Kelley (b) (4)	15 Sep 2020 00:43:39
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	15 Sep 2020 00:43:44
User entered empty.	System	15 Sep 2020 00:43:39

US3032204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 22:04:04
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:57
User entered '14 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 22:04:04
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 23:06:24
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 23:06:24
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 23:06:24
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '17:46'	(b) (4) Linden DeBoer (b) (4)	14 Sep 2020 23:06:24
	(b) (4)	

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Sep 2020 17:46'	System	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:29
User entered 'ONCE'	System	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 23:06:24

US3032204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:42:10

US3032204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:42:10

US3032204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '16:53'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:42:10

US3032204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Sep 2020 16:53'	System	15 Sep 2020 00:42:10

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '14 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '16:42'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '14 Sep 2020 16:42'	System	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	15 Sep 2020 00:41:28

US3032204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:27:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 00:41:37

US3032204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	15 Sep 2020 00:41:37

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:20:35', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c569381f-7d69-4b43-aa74-a80994bd9df1'	System	14 Sep 2020 23:21:06
User entered 'Yes (Y)'	System	14 Sep 2020 23:21:06

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:20:43', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c569381f-7d69-4b43-aa74-a80994bd9df1'	System	14 Sep 2020 23:21:06
User entered '97.5'	System	14 Sep 2020 23:21:06

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:20:48', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c569381f-7d69-4b43-aa74-a80994bd9df1'	System	14 Sep 2020 23:21:06
User entered 'No (N)'	System	14 Sep 2020 23:21:06

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:20:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c569381f-7d69-4b43-aa74-a80994bd9df1'	System	14 Sep 2020 23:21:06
User entered '14 Sep 2020 18:20'	System	14 Sep 2020 23:21:06

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 20:36'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:33:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '94b3a24c-19c6-4f64-ae31-d691eaf8df75'	System	15 Sep 2020 02:35:00
User entered 'Yes (Y)'	System	15 Sep 2020 02:35:00

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:34:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '94b3a24c-19c6-4f64-ae31-d691eaf8df75'	System	15 Sep 2020 02:35:00
User entered '97.1'	System	15 Sep 2020 02:35:00

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:34:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '94b3a24c-19c6-4f64-ae31-d691eaf8df75'	System	15 Sep 2020 02:35:00
User entered 'No (N)'	System	15 Sep 2020 02:35:00

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:34:30', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '94b3a24c-19c6-4f64-ae31-d691eaf8df75'	System	15 Sep 2020 02:35:00
User entered '14 Sep 2020 21:34'	System	15 Sep 2020 02:35:00

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 21:31'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 2'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:13:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aae5b745-8487-436a-b93a-14543216561f'	System	15 Sep 2020 21:13:51
User entered 'Yes (Y)'	System	15 Sep 2020 21:13:51

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:13:35', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aae5b745-8487-436a-b93a-14543216561f'	System	15 Sep 2020 21:13:51
User entered '96.7'	System	15 Sep 2020 21:13:51

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:13:40', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aae5b745-8487-436a-b93a-14543216561f'	System	15 Sep 2020 21:13:51
User entered 'No (N)'	System	15 Sep 2020 21:13:51

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:13:47', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'aae5b745-8487-436a-b93a-14543216561f'	System	15 Sep 2020 21:13:51
User entered '15 Sep 2020 16:13'	System	15 Sep 2020 21:13:51

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 3'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db444385-90b9-4da8-8cbd-1ca7866261ca'	System	16 Sep 2020 21:09:30
User entered 'Yes (Y)'	System	16 Sep 2020 21:09:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:17', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db444385-90b9-4da8-8cbd-1ca7866261ca'	System	16 Sep 2020 21:09:30
User entered '97.0'	System	16 Sep 2020 21:09:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db444385-90b9-4da8-8cbd-1ca7866261ca'	System	16 Sep 2020 21:09:30
User entered 'No (N)'	System	16 Sep 2020 21:09:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'db444385-90b9-4da8-8cbd-1ca7866261ca'	System	16 Sep 2020 21:09:30
User entered '16 Sep 2020 16:09'	System	16 Sep 2020 21:09:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 4'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:24:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '938c8585-71a0-4134-a4c8-a60f7a576e29'	System	17 Sep 2020 21:25:36
User entered 'Yes (Y)'	System	17 Sep 2020 21:25:36

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '938c8585-71a0-4134-a4c8-a60f7a576e29'	System	17 Sep 2020 21:25:36
User entered '97.9'	System	17 Sep 2020 21:25:36

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '938c8585-71a0-4134-a4c8-a60f7a576e29'	System	17 Sep 2020 21:25:36
User entered 'No (N)'	System	17 Sep 2020 21:25:36

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '938c8585-71a0-4134-a4c8-a60f7a576e29'	System	17 Sep 2020 21:25:36
User entered '17 Sep 2020 16:25'	System	17 Sep 2020 21:25:36

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 5'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:07:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '95e07108-792a-4861-8e25-3716217f1100'	System	18 Sep 2020 22:08:30
User entered 'Yes (Y)'	System	18 Sep 2020 22:08:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:10', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '95e07108-792a-4861-8e25-3716217f1100'	System	18 Sep 2020 22:08:30
User entered '97.5'	System	18 Sep 2020 22:08:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '95e07108-792a-4861-8e25-3716217f1100'	System	18 Sep 2020 22:08:30
User entered 'No (N)'	System	18 Sep 2020 22:08:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:25', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '95e07108-792a-4861-8e25-3716217f1100'	System	18 Sep 2020 22:08:30
User entered '18 Sep 2020 17:08'	System	18 Sep 2020 22:08:30

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 6'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:28:35', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '83446f34-0179-4eb9-a769-b8cf2de32621'	System	20 Sep 2020 02:29:22
User entered 'Yes (Y)'	System	20 Sep 2020 02:29:22

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:12', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '83446f34-0179-4eb9-a769-b8cf2de32621' User entered '97.3'	System	20 Sep 2020 02:29:22
	System	20 Sep 2020 02:29:22

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:16', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '83446f34-0179-4eb9-a769-b8cf2de32621'	System	20 Sep 2020 02:29:22
User entered 'No (N)'	System	20 Sep 2020 02:29:22

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:19', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '83446f34-0179-4eb9-a769-b8cf2de32621'	System	20 Sep 2020 02:29:22
User entered '19 Sep 2020 21:29'	System	20 Sep 2020 02:29:22

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 7'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:06:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '2babb05e-7c4a-42c6-92e8-eb2b4600a1a1'	System	21 Sep 2020 02:07:18
User entered 'Yes (Y)'	System	21 Sep 2020 02:07:18

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '2babb05e-7c4a-42c6-92e8-eb2b4600a1a1' User entered '97.1'	System	21 Sep 2020 02:07:18
	System	21 Sep 2020 02:07:18

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '2babb05e-7c4a-42c6-92e8-eb2b4600a1a1'	System	21 Sep 2020 02:07:18
User entered 'No (N)'	System	21 Sep 2020 02:07:18

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:16', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '2babb05e-7c4a-42c6-92e8-eb2b4600a1a1' User entered '20 Sep 2020 21:07'	System	21 Sep 2020 02:07:18
	System	21 Sep 2020 02:07:18

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bb39c8b0-9a75-4e70-a575-d4fa838f7110'	System	14 Sep 2020 23:21:41
User entered 'None (1)'	System	14 Sep 2020 23:21:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bb39c8b0-9a75-4e70-a575-d4fa838f7110'	System	14 Sep 2020 23:21:41
User entered 'No (N)'	System	14 Sep 2020 23:21:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bb39c8b0-9a75-4e70-a575-d4fa838f7110'	System	14 Sep 2020 23:21:41
User entered 'No (N)'	System	14 Sep 2020 23:21:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bb39c8b0-9a75-4e70-a575-d4fa838f7110'	System	14 Sep 2020 23:21:41
User entered 'None (1)'	System	14 Sep 2020 23:21:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bb39c8b0-9a75-4e70-a575-d4fa838f7110'	System	14 Sep 2020 23:21:41
User entered '14 Sep 2020 18:21'	System	14 Sep 2020 23:21:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 20:36'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:34:57', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '32d8ca53-5c25-416f-b4ae-c8efc8d3c78e'	System	15 Sep 2020 02:36:46
User entered 'None (1)'	System	15 Sep 2020 02:36:46

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:36:22', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '32d8ca53-5c25-416f-b4ae-c8efc8d3c78e'	System	15 Sep 2020 02:36:46
User entered 'No (N)'	System	15 Sep 2020 02:36:46

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:36:33', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '32d8ca53-5c25-416f-b4ae-c8efc8d3c78e'	System	15 Sep 2020 02:36:46
User entered 'No (N)'	System	15 Sep 2020 02:36:46

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:36:38', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '32d8ca53-5c25-416f-b4ae-c8efc8d3c78e'	System	15 Sep 2020 02:36:46
User entered 'None (1)'	System	15 Sep 2020 02:36:46

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:36:44', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '32d8ca53-5c25-416f-b4ae-c8efc8d3c78e'	System	15 Sep 2020 02:36:46
User entered '14 Sep 2020 21:36'	System	15 Sep 2020 02:36:46

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 21:31'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 2'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:13:59', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '707322b9-e120-45d0-9a9d-62cedcfcfb7c'	System	15 Sep 2020 21:14:16
User entered 'None (1)'	System	15 Sep 2020 21:14:16

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '707322b9-e120-45d0-9a9d-62cedcfcfb7c'	System	15 Sep 2020 21:14:16
User entered 'No (N)'	System	15 Sep 2020 21:14:16

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '707322b9-e120-45d0-9a9d-62cedcfcfb7c'	System	15 Sep 2020 21:14:16
User entered 'No (N)'	System	15 Sep 2020 21:14:16

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '707322b9-e120-45d0-9a9d-62cedcfcfb7c'	System	15 Sep 2020 21:14:16
User entered 'None (1)'	System	15 Sep 2020 21:14:16

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:13', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '707322b9-e120-45d0-9a9d-62cedcfcfb7c'	System	15 Sep 2020 21:14:16
User entered '15 Sep 2020 16:14'	System	15 Sep 2020 21:14:16

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 3'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e31d9db5-a6a0-47f1-8205-cf1dc6a0f999'	System	16 Sep 2020 21:09:53
User entered 'None (1)'	System	16 Sep 2020 21:09:53

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e31d9db5-a6a0-47f1-8205-cf1dc6a0f999'	System	16 Sep 2020 21:09:53
User entered 'No (N)'	System	16 Sep 2020 21:09:53

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:42', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e31d9db5-a6a0-47f1-8205-cf1dc6a0f999'	System	16 Sep 2020 21:09:53
User entered 'No (N)'	System	16 Sep 2020 21:09:53

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:46', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e31d9db5-a6a0-47f1-8205-cf1dc6a0f999'	System	16 Sep 2020 21:09:53
User entered 'None (1)'	System	16 Sep 2020 21:09:53

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:49', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e31d9db5-a6a0-47f1-8205-cf1dc6a0f999'	System	16 Sep 2020 21:09:53
User entered '16 Sep 2020 16:09'	System	16 Sep 2020 21:09:53

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 4'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd5eb480c-ceed-433a-a557-1f60e5d28ce9'	System	17 Sep 2020 21:25:58
User entered 'None (1)'	System	17 Sep 2020 21:25:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd5eb480c-ceea-433a-a557-1f60e5d28ce9'	System	17 Sep 2020 21:25:58
User entered 'No (N)'	System	17 Sep 2020 21:25:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd5eb480c-ceed-433a-a557-1f60e5d28ce9'	System	17 Sep 2020 21:25:58
User entered 'No (N)'	System	17 Sep 2020 21:25:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd5eb480c-ceed-433a-a557-1f60e5d28ce9'	System	17 Sep 2020 21:25:58
User entered 'None (1)'	System	17 Sep 2020 21:25:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:25:55', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'd5eb480c-ceeda-433a-a557-1f60e5d28ce9'	System	17 Sep 2020 21:25:58
User entered '17 Sep 2020 16:25'	System	17 Sep 2020 21:25:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 5'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e2033f18-883a-401b-a486-201296b27e58'	System	18 Sep 2020 22:08:58
User entered 'None (1)'	System	18 Sep 2020 22:08:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e2033f18-883a-401b-a486-201296b27e58'	System	18 Sep 2020 22:08:58
User entered 'No (N)'	System	18 Sep 2020 22:08:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:44', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e2033f18-883a-401b-a486-201296b27e58'	System	18 Sep 2020 22:08:58
User entered 'No (N)'	System	18 Sep 2020 22:08:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:47', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e2033f18-883a-401b-a486-201296b27e58'	System	18 Sep 2020 22:08:58
User entered 'None (1)'	System	18 Sep 2020 22:08:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:54', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'e2033f18-883a-401b-a486-201296b27e58'	System	18 Sep 2020 22:08:58
User entered '18 Sep 2020 17:08'	System	18 Sep 2020 22:08:58

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 6'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b82c52a8-4a93-483c-b9bf-aff6cc4a924'	System	20 Sep 2020 02:29:40
User entered 'None (1)'	System	20 Sep 2020 02:29:40

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b82c52a8-4a93-483c-b9bf-aff6cc4a924'	System	20 Sep 2020 02:29:40
User entered 'No (N)'	System	20 Sep 2020 02:29:40

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:32', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b82c52a8-4a93-483c-b9bf-aff6cc4a924'	System	20 Sep 2020 02:29:40
User entered 'No (N)'	System	20 Sep 2020 02:29:40

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:35', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b82c52a8-4a93-483c-b9bf-aff6cc4a924'	System	20 Sep 2020 02:29:40
User entered 'None (1)'	System	20 Sep 2020 02:29:40

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:39', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b82c52a8-4a93-483c-b9bf-aff6cc4a924'	System	20 Sep 2020 02:29:40
User entered '19 Sep 2020 21:29'	System	20 Sep 2020 02:29:40

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 7'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:23', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'cfd6ed58-b271-411e-b2c4-f055b7ee8f19'	System	21 Sep 2020 02:07:41
User entered 'None (1)'	System	21 Sep 2020 02:07:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'cfd6ed58-b271-411e-b2c4-f055b7ee8f19'	System	21 Sep 2020 02:07:41
User entered 'No (N)'	System	21 Sep 2020 02:07:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'cfd6ed58-b271-411e-b2c4-f055b7ee8f19'	System	21 Sep 2020 02:07:41
User entered 'No (N)'	System	21 Sep 2020 02:07:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:32', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'cfd6ed58-b271-411e-b2c4-f055b7ee8f19'	System	21 Sep 2020 02:07:41
User entered 'None (1)'	System	21 Sep 2020 02:07:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:35', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'cfd6ed58-b271-411e-b2c4-f055b7ee8f19'	System	21 Sep 2020 02:07:41
User entered '20 Sep 2020 21:07'	System	21 Sep 2020 02:07:41

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:42', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:49', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:52', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:55', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:21:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'None (0)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:22:03', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered 'No (N)'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T18:22:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'dd3ed8b7-adbf-4b5e-8f85-285f5e5ffd0f'	System	14 Sep 2020 23:22:10
User entered '14 Sep 2020 18:22'	System	14 Sep 2020 23:22:10

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 18:06'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 20:36'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:36:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'None (0)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:39', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered 'No (N)'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-14T21:37:43', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '08dec830-2e0a-40d5-afc7-5bbf1decc2d2'	System	15 Sep 2020 02:37:48
User entered '14 Sep 2020 21:37'	System	15 Sep 2020 02:37:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '14 Sep 2020 21:31'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 2'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:27', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:30', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:34', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'None (0)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:41', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered 'No (N)'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-15T16:14:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c1c8481f-798e-47e7-bbf8-00cda1a785c6'	System	15 Sep 2020 21:14:48
User entered '15 Sep 2020 16:14'	System	15 Sep 2020 21:14:48

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 3'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:09:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:04', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:12', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'None (0)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:19', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered 'No (N)'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-16T16:10:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '65baf911-4a49-418b-8c3e-2fb85326c297'	System	16 Sep 2020 21:10:28
User entered '16 Sep 2020 16:10'	System	16 Sep 2020 21:10:28

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 4'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:00', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:12', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:15', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'None (0)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered 'No (N)'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-17T16:26:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'abaa2904-7394-4a55-b13f-178120404dc7'	System	17 Sep 2020 21:26:26
User entered '17 Sep 2020 16:26'	System	17 Sep 2020 21:26:26

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 5'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:08:59', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:09', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:14', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'None (0)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered 'No (N)'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-18T17:09:20', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9d540248-4404-4ad2-9076-8900c5397079'	System	18 Sep 2020 22:09:24
User entered '18 Sep 2020 17:09'	System	18 Sep 2020 22:09:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 6'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:43', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:46', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:49', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:52', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:54', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:29:57', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'None (0)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:30:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered 'No (N)'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-19T21:30:05', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '89313957-dbab-4640-b7b7-9d5dce449301'	System	20 Sep 2020 02:30:08
User entered '19 Sep 2020 21:30'	System	20 Sep 2020 02:30:08

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Sep 2020 23:06:24
User entered 'Day 7'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:40', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:42', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:44', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:46', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:49', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'None (0)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:07:58', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered 'No (N)'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-09-20T21:08:01', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '9301defc-6485-4834-a373-7534514a395a'	System	21 Sep 2020 02:08:03
User entered '20 Sep 2020 21:08'	System	21 Sep 2020 02:08:03

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 23:06:24

US3032204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:51:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 23:06:24

US3032204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Christy Lee (b) (4) (b) (4)	21 Sep 2020 22:28:20

US3032204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered '21 Sep 2020'	(b) (4) Christy Lee (b) (4) (b) (4)	21 Sep 2020 22:28:20

US3032204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christy Lee (b) (4) (b) (4)	21 Sep 2020 22:28:20

US3032204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered empty.	(b) (4) Christy Lee (b) (4) (b) (4)	21 Sep 2020 22:28:20

US3032204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:30:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Christy Lee (b) (4) (b) (4)	21 Sep 2020 22:28:29

US3032204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	21 Sep 2020 22:28:29

US3032204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Oct 2020 21:43:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 21:43:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Oct 2020 21:43:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Oct 2020 21:43:04
User entered empty.	System	05 Oct 2020 21:43:04
	Kelsey Kelley (b) (4)	05 Oct 2020 21:43:04
	(b) (4)	

US3032204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered '28 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:43:04

US3032204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:43:04

US3032204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:43:04

US3032204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:43:20

US3032204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	05 Oct 2020 21:43:20

US3032204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:44:59

US3032204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:44:59

US3032204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:44:59

US3032204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:02
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:44:59

US3032204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:31:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:36:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 21:45:05

US3032204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	05 Oct 2020 21:45:05

US3032204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:33:27
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:12:21

US3032204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:33:27
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '12 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:12:21

US3032204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.		02 Dec 2020 16:33:27
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:12:21

US3032204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'VISIT3'	System	12 Oct 2020 22:12:21

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '12 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '16:26'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '12 Oct 2020 16:26'	System	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:09
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '84'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	12 Oct 2020 22:13:00

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:19

US3032204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '12 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:13:19

US3032204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:14:02

US3032204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '12 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:14:02

US3032204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:40
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered '16:34'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:14:02

US3032204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '12 Oct 2020 16:34'	System	12 Oct 2020 22:14:02

US3032204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:34:44
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Oct 2020 22:14:04

US3032204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	12 Oct 2020 22:14:04

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 64'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-15T19:08:51', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '23a5984e-d1c9-4249-9219-3b19eecbf6b2'	System	16 Oct 2020 00:09:17
User entered 'No (N)'	System	16 Oct 2020 00:09:17

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-15T19:09:02', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '23a5984e-d1c9-4249-9219-3b19eecbf6b2'	System	16 Oct 2020 00:09:17
User entered 'No (N)'	System	16 Oct 2020 00:09:17

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-15T19:09:12', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: '23a5984e-d1c9-4249-9219-3b19eecbf6b2'	System	16 Oct 2020 00:09:17
User entered '15 Oct 2020 19:09:12'	System	16 Oct 2020 00:09:17

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 71'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-22T21:49:18', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bef5aba9-773a-47f0-8618-d342cad1297c'	System	23 Oct 2020 02:49:37
User entered 'No (N)'	System	23 Oct 2020 02:49:37

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-22T21:49:23', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bef5aba9-773a-47f0-8618-d342cad1297c'	System	23 Oct 2020 02:49:37
User entered 'No (N)'	System	23 Oct 2020 02:49:37

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-22T21:49:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'bef5aba9-773a-47f0-8618-d342cad1297c' User entered '22 Oct 2020 21:49:31'	System	23 Oct 2020 02:49:37
	System	23 Oct 2020 02:49:37

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 78'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-29T19:27:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b4cceaeb-c747-4c24-9eef-2cdb98dc1d1f'	System	30 Oct 2020 00:27:36
User entered 'No (N)'	System	30 Oct 2020 00:27:36

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-29T19:27:21', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b4cceaeb-c747-4c24-9eef-2cdb98dc1d1f'	System	30 Oct 2020 00:27:36
User entered 'No (N)'	System	30 Oct 2020 00:27:36

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-10-29T19:27:29', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'b4cceaeb-c747-4c24-9eef-2cdb98dc1d1f' User entered '29 Oct 2020 19:27:29'	System	30 Oct 2020 00:27:36
	System	30 Oct 2020 00:27:36

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 92'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:51:08', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'Yes (Y)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:51:26', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'Yes (Y)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Please 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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:51:37', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:51:45', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'Yes (Y)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '1'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '0'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '1'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '0'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '0'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '0'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '0'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:06', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered '0'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Please 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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:11', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:24', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'Yes (Y)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Please 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 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:28', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d'	System	12 Nov 2020 21:52:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a3aff300de7a6458)', Time: '2020-11-12T15:52:31', User OID: 'PatientReportedOutcome (US3032204)', ODM File OID: 'c673636c-640a-4c21-b2b6-87ba64e88f6d' User entered '12 Nov 2020 15:52:31'	System	12 Nov 2020 21:52:44
	System	12 Nov 2020 21:52:44

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:51:25
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48
Data entry locked.	System	14 Aug 2020 17:03:03
User entered 'Day 99'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:48
Data entry locked.	System	14 Aug 2020 17:03:03
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:03:03

US3032204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	02 Dec 2020 16:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:37:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:07:08

US3032204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:37:40
User entered '06 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:07:08

US3032204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:37:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:07:08

US3032204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		02 Dec 2020 16:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:37:40
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:07:08

US3032204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:29:25
User closed query 'Per CDM: Please note that the end of study form is completed. If the next safety call did not occur, then please update this field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 08:54:51
Query 'Per CDM: Please note that the end of study form is completed. If the next safety call did not occur, then please update this field accordingly.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:44:04
DataPoint Un-verified.	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:43:58
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:43:58
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:43:58
User opened query 'Per CDM: Please note that the end of study form is completed. If the next safety call did not occur, then please update this field accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:10:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:40:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Nov 2020 21:37:40
User entered 'Yes (Y)'	Russell Herstein (b) (4) (b) (4)	10 Nov 2020 14:07:17

US3032204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	09 Jan 2021 16:43:58
User entered '1'	System	10 Nov 2020 14:07:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:51:24
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Please reconcile and add severity page as required' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 03:41:07
Query 'Please reconcile and add severity page as required' answered with 'data updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:26:11
User opened query 'Please reconcile and add severity page as required' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:08:36
User entered '11 Nov 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:14:48

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:53

[Time of Contact](#)

Audit	User	Time (GMT)	
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58	
DataPoint Verified.	(b) (4)	16 Dec 2020 14:49:18	
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46	
User closed query 'Per the source the time is 07:00 please update to reflect the source' (Site from CRA).	(b) (4)	(b) (4), (b) (6)	24 Nov 2020 17:35:46
Query 'Per the source the time is 07:00 please update to reflect the source' answered with 'updated' (Site from CRA).	Russell Herstein (b) (4)	(b) (4)	24 Nov 2020 16:33:18
Signature has been broken.	Russell Herstein (b) (4)	(b) (4)	24 Nov 2020 16:33:15
User entered '07:00' reason for change: Data Entry Error	Russell Herstein (b) (4)	(b) (4)	24 Nov 2020 16:33:15
User opened query 'Per the source the time is 07:00 please update to reflect the source' (Site from CRA).	(b) (4), (b) (6)	(b) (4)	23 Nov 2020 23:47:06
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	20 Nov 2020 16:29:59
User entered '15:00'	Kelsey Kelley (b) (4)	(b) (4)	11 Nov 2020 22:14:48

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '11 Nov 2020 07:00'	System	24 Nov 2020 16:33:15
User entered '11 Nov 2020 15:00'	System	11 Nov 2020 22:14:48

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:52:53
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:14:48

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:52:55
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:14:48

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Please reconcile and add Day 1 09Nov2020 on line 8 as required' (Site from CRA).	(b) (4)	20 Nov 2020 03:38:52
Query 'Please reconcile and add Day 1 09Nov2020 on line 8 as required' answered with 'data updated' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:38:52
Query 'Please reconcile and add Day 1 09Nov2020 on line 8 as required' answered with 'data updated' (Site from CRA).	Linden DeBoer (b) (4)	19 Nov 2020 16:25:12
User opened query 'Please reconcile and add Day 1 09Nov2020 on line 8 as required' (Site from CRA).	(b) (4)	19 Nov 2020 05:29:21
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	19 Nov 2020 05:29:21
	Kelsey Kelley (b) (4)	11 Nov 2020 22:17:07
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
Query 'Per the source the symptom onset was 9NOV20 please update ' canceled (Site from CRA).		23 Nov 2020 23:49:53
User opened query 'Per the source the symptom onset was 9NOV20 please update ' (Site from CRA).		23 Nov 2020 23:48:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:48:56
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:48:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:35:57
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:06
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:09
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:13
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:15
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:36:24
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:27
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:40
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:36:45
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:36:47
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:36:55
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:17:07

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 3 (Day 3)'	Kelsey Kelley (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:57:40
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:57:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:57:43
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '96'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:57:46
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '37.0' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:57:47
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:57:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:57:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:57:53
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:57:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:01
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:58:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:58:04
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:07
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:10
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:58:11
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 23:58:13
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:14
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:16
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 23:58:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:18:38

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '12 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:01:24
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:59:26
DataPoint Un-verified.	Linden DeBoer (b) (4)	24 Nov 2020 22:49:38
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 22:49:38
User entered '94' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 22:49:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User closed query 'Per the source O2 saturation is listed a 95% please update' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:17:43 24 Nov 2020 18:41:41
Query 'Per the source O2 saturation is listed a 95% please update' answered with 'DATA UPDATE' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:38
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:29
User entered '95' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:29
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 00:01:22
DataPoint Verified.		24 Nov 2020 00:01:20
User opened query 'Per the source O2 saturation is listed a 95% please update' (Site from CRA). User signature succeeded.		24 Nov 2020 00:01:01
User entered '94'	Keith Vrbicky (b) (4) (b) (4) Kelsey Kelley (b) (4) (b) (4)	20 Nov 2020 16:29:59 12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:01:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '98.6' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:38:37
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:39
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:38:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:38:09
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:38:11
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:51
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:38:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:39:13
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:39:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:39:53
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:39:55
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:58:17

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:03:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '13 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:04:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:05:17
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '95'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:05:18
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '99.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:50:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:50:46
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:50:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:01
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:51:03
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:10
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:14
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:17
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:27
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:29
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:33
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:51:36
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:51:39
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:51:10

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 6 (Day 6)'	Kelsey Kelley (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:10:01
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '14 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:10:04
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:09:31
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Re-query: Noted previous response but this is still mandatory to be entered on the severity page within 24 hrs of result' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 03:40:59
Query 'Re-query: Noted previous response but this is still mandatory to be entered on the severity page within 24 hrs of result' answered with 'data has been entered' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:43
User opened query 'Re-query: Noted previous response but this is still mandatory to be entered on the severity page within 24 hrs of result' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 05:28:39
User closed query 'Please ensure this is captured on severity log. Leave end date on severity log blank for SpO2 % <=/ 93% since it is present as of last symptom log entry' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 05:28:39
Query 'Please ensure this is captured on severity log. Leave end date on severity log blank for SpO2 % <=/ 93% since it is present as of last symptom log entry' answered with 'NOTED - END DATE NOT CAPTURED AT THIS TIME' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	17 Nov 2020 22:45:16
User opened query 'Please ensure this is captured on severity log. Leave end date on severity log blank for SpO2 % <=/ 93% since it is present as of last symptom log entry' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:12:22
User entered '87'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:09:57
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '99.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:46
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:06:57
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:10
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:11
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:13
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:08:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:08:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:57
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:07:55
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:52:58

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 7 (Day 7)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:31:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '15 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:03
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:10:30
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '91'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:10:31
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '99.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:59:26
DataPoint Un-verified.	Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:36:01
User closed query 'Per the source the symptom log states "Mild" please update' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:36:00
Query 'Per the source the symptom log states "Mild" please update' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:26:10
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:59
User opened query 'Per the source the symptom log states "Mild" please update' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 00:13:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 17:36:19
DataPoint Un-verified.		24 Nov 2020 00:14:41
DataPoint Verified.		24 Nov 2020 00:14:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	24 Nov 2020 17:36:07
User closed query 'Per the source symptom log list "Moderate"' (Site from CRA).		24 Nov 2020 17:36:06
Query 'Per the source symptom log list "Moderate"' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4)	24 Nov 2020 16:26:19
Signature has been broken.	(b) (4)	
	Russell Herstein (b) (4)	24 Nov 2020 16:25:59
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Russell Herstein (b) (4)	24 Nov 2020 16:25:59
User opened query 'Per the source symptom log list "Moderate"' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 00:33:08
		24 Nov 2020 00:14:28
DataPoint Verified.		24 Nov 2020 00:14:24
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
	(b) (4)	
User entered 'None (None)'	Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:59:26
DataPoint Un-verified.	Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 22:57:49
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:36:13
User closed query 'Per the source symptom list "None" please update' (Site from CRA).		24 Nov 2020 17:36:10
Query 'Per the source symptom list "None" please update' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:26:27
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:59
User entered 'None (None)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	24 Nov 2020 16:25:59
User opened query 'Per the source symptom list "None" please update' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 00:33:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (u), (v), (b) (6)	24 Nov 2020 17:36:16
User closed query 'Per the source the symptom log list "Severe" please update' (Site from CRA).		24 Nov 2020 17:36:14
Query 'Per the source the symptom log list "Severe" please update' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4)	24 Nov 2020 16:26:41
Signature has been broken.	Russell Herstein (b) (4)	24 Nov 2020 16:25:59
User entered 'Severe (Severe)' reason for change:	(b) (4)	
Data Entry Error	Russell Herstein (b) (4)	24 Nov 2020 16:25:59
User opened query 'Per the source the symptom log list "Severe" please update' (Site from CRA).	(b) (4)	
Query 'Per the source symptom log list "Mild" please update' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 00:39:19
User opened query 'Per the source symptom log list "Mild" please update' (Site from CRA).		24 Nov 2020 00:38:21
User opened query 'Per the source symptom log list "Mild" please update' (Site from CRA).		24 Nov 2020 00:36:57
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 17:36:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:36:25
User closed query 'Per the source the symptom log list "Mild" ' (Site from CRA).		24 Nov 2020 17:36:23
Query 'Per the source the symptom log list "Mild" ' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4)	24 Nov 2020 16:26:33
Signature has been broken.	(b) (4)	24 Nov 2020 16:25:59
	Russell Herstein (b) (4)	24 Nov 2020 16:25:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 16:25:59
User opened query 'Per the source the symptom log list "Mild" ' (Site from CRA).	Russell Herstein (b) (4)	24 Nov 2020 00:40:52
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 00:39:33
DataPoint Verified.		24 Nov 2020 00:39:30
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
	(b) (4)	
User entered 'None (None)'	Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:41:01
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:06
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:14
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:25
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:32
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:41:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:01

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:37:40
Query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis.' answered with 'subject passed away on 16Nove2020. please see end of study' (Site from CRA).	Samantha Wieseler (b) (4)	04 Dec 2020 22:38:32
User opened query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 23:42:49
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 8 (Day 8)'	Kelsey Kelley (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:43:08
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '16 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:47:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:42:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '93'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:42:54
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '97.3' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:44:47
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:44:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:44:50
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:35
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:38
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:45
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:47:44
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:47:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:40
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:47:39
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:37
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:33
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:59:38
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:59:33
User entered 'Severe (Severe)'	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:54:34
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:30
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:47:31
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:47:28
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:54:34

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Day 1 (Day 1)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '09 Nov 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '%'	System	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Severe (Severe)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:24:49

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:51:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 22:59:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	19 Nov 2020 16:24:49
	(b) (4)	

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Please reconcile as positive results received from central lab' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 03:40:51
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 04:57:37
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'UPDATED' (Site from System).	Russell Herstein (b) (4) (b) (4)	17 Nov 2020 22:45:55
Query 'Please reconcile as positive results received from central lab' answered with 'UPDATED' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	17 Nov 2020 22:45:50
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	17 Nov 2020 22:45:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	17 Nov 2020 22:45:38
User opened query 'Please reconcile as positive results received from central lab' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:09:08
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:48:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:51:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	17 Nov 2020 22:45:38
User entered '0'	System	11 Nov 2020 22:19:51

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:17
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:15
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Start Date](#)

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User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered '14 Nov 2020'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User closed query 'Please consider updating end date to 17Nov2020 as it was ongoing at the time of subject's death' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:57:53
Query 'Please consider updating end date to 17Nov2020 as it was ongoing at the time of subject's death' answered with 'data updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 22:55:22
User entered '16 Nov 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 22:55:14
User opened query 'Please consider updating end date to 17Nov2020 as it was ongoing at the time of subject's death' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:40:38
User entered '14 Nov 2020'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered '87'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

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User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[PaO2](#)

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Did the subject have Respiratory failure?](#)

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User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 14:51:53

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[High-Flow Oxygen?](#)

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US3032204

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US3032204

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

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[Non-Invasive Ventilation?](#)

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US3032204

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US3032204

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US3032204

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[Mechanical Ventilation?](#)

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User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

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US3032204

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US3032204

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[ECMO?](#)

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US3032204

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Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
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US3032204

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US3032204

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Evidence of Shock Requires Vasopressors](#)

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US3032204

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US3032204

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US3032204

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Generated On: 09 Jun 2021 14:51:53

[Acute Renal Dysfunction?](#)

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US3032204

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US3032204

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Generated On: 09 Jun 2021 14:51:53

[Hepatic Dysfunction?](#)

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US3032204

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Generated On: 09 Jun 2021 14:51:53

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US3032204

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Generated On: 09 Jun 2021 14:51:53

[Neurologic Dysfunction?](#)

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US3032204

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Clinical Evidence](#)

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Date of Assessment](#)

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Radiographical Evidence](#)

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

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US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Admission to an intensive care unit due to SARS-CoV-2](#)

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Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:51:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:52:18
User entered empty.	Linden DeBoer (b) (4) (b) (4)	19 Nov 2020 16:22:26

US3032204

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:51:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:52:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:14:52

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per ETRTR, According to PPD labs, Saliva collection samples have not been received/collected, except for Day 9 sample. Please fup.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 13:25:48
Query 'Per ETRTR, According to PPD labs, Saliva collection samples have not been received/collected, except for Day 9 sample. Please fup.' answered with 'sample was shipped' (Site from CRA).	Kelsey Kelley (b) (4)	11 Dec 2020 15:30:49
User opened query 'Per ETRTR, According to PPD labs, Saliva collection samples have not been received/collected, except for Day 9 sample. Please fup.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 23:45:03
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:51:53

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 13nov2020 for Day 3 in EDC, however 13nov2020 is reported under "Day 9" (Accession # 1F637928592) in PPD Central lab. Please review and confirm the correct Visit Day in the response and update EDC or PPD Central Labs. (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:08:33
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 13nov2020 for Day 3 in EDC, however 13nov2020 is reported under "Day 9" (Accession # 1F637928592) in PPD Central lab. Please review and confirm the correct Visit Day in the response and update EDC or PPD Central Labs. answered with 'Day 3 not Day9' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:36:35
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 13nov2020 for Day 3 in EDC, however 13nov2020 is reported under "Day 9" (Accession # 1F637928592) in PPD Central lab. Please review and confirm the correct Visit Day in the response and update EDC or PPD Central Labs. (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:20:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '13 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:51:53

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD, the tracking number information is also needed alongwith the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response.' (Site from DM).		25 Jan 2021 08:06:38
Query 'Per GCL Lab Reconciliation Requery: Saliva: Samantha Wieseler Per response, since the sample is still missing in PPD, the tracking number information is also needed alongwith the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response.' answered with 'Accession Number: 1F68048' (Site from DM).	(b) (4) (b) (4)	22 Jan 2021 21:16:36
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD, the tracking number information is also needed alongwith the Accession number, to track the sample in PPD. Please provide the tracking number with shipping date in the response.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:32:49
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:32:49
Query 'Per GCL Lab Reconciliation Requery: Saliva: Samantha Wieseler Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'accession number is what was asked for a provided, please utilize to find info needed' (Site from DM).	(b) (4) (b) (4)	20 Jan 2021 22:35:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:20:12
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Since the sample was shipped, please provide the Accession number to track the sample in PPD as the sample is still missing in PPD' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:20:12
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Since the sample was shipped, please provide the Accession number to track the sample in PPD as the sample is still missing in PPD' answered with 'Accession Number: 1F68048' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 23:47:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, Since the sample was shipped, please provide the Accession number to track the sample in PPD as the sample is still missing in PPD' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 09:21:54
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:25:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample shipped' (Site from DM).	Kelsey Kelley (b) (4)	11 Dec 2020 15:26:53

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query'	(b) (4), (b) (6)	07 Dec 2020 04:55:54
Per GCL Lab Reconciliation: Saliva: Sample dated 09SEP2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).		07 Dec 2020 04:55:50
User opened query ' Per GCL Lab Reconciliation: Saliva: Sample dated 09SEP2020 is recorded under Illness Visit Day 9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		07 Dec 2020 04:55:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '15 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:51:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:51:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:55:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:33:45

US3032204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'SICKD1'	System	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 03:11:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '15:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '11 Nov 2020 15:25'	System	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:53:59
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '203.2' cm	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:10:40
DataPoint set to visible.	(b) (4) System	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:15
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '117.9' kg	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:10:40
DataPoint set to visible.	(b) (4) System	11 Nov 2020 22:09:53

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '37.0' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:24
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:22
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'bpm'	System	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:30
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'breaths/min'	System	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:37
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered 'mmHg'	System	11 Nov 2020 22:10:40

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:44
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:11:29

US3032204

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:44
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:11:29

US3032204

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:51:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:11:37

US3032204

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:51:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:54:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:11:37

US3032204

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:51:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per CDM: there is an event recorded as Fatal. Please ensure applicable forms within the End of Study/Study Discontinuation Folder is completed.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:22:34
Query 'Per CDM: there is an event recorded as Fatal. Please ensure applicable forms within the End of Study/Study Discontinuation Folder is completed.' answered with 'data was entered' (Site from DM). User opened query 'Per CDM: there is an event recorded as Fatal. Please ensure applicable forms within the End of Study/Study Discontinuation Folder is completed.' (Site from DM). User signature succeeded.	Linden DeBoer (b) (4) (b) (4)	23 Nov 2020 16:59:33
Signature has been broken.	(b) (4), (b) (6)	19 Nov 2020 22:39:24
User entered 'Yes (Y)' reason for change: Data Entry Error User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:59:00
	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 21:59:00
	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:34:16
	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:27:10

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:53:05
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:22
User entered 'USA-US032-2020-mRNA-1273-P301000012'	System	18 Nov 2020 18:46:17
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 18:46:17

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User closed query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 00:53:30
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:18:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:18:00
Data point term sent to Coder	System	22 Mar 2021 21:17:08
Query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' answered with 'updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:16:49
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:16:25
Coding entries removed.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:16:25
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:16:25
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:16:25
User opened query 'Per CDM: Site reports subject had Symptomatic Covid-19. Please verify data and update AE term to 'Symptomatic Covid-19' to align with page 7 of v5.0 of CCGs, "AE term should be 'Symptomatic Covid-19' if symptomatic". Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:30:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:53:02
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Please verify if this should be COVID-19 as positive results received' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:06:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:15:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 22:15:50
Data point term sent to Coder	System	17 Nov 2020 22:00:14
Query 'Please verify if this should be COVID-19 as positive results received' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:59:57
Coding entries removed.		17 Nov 2020 21:59:49
User entered 'COVID-19' reason for change: Data Entry Error		17 Nov 2020 21:59:49
User opened query 'Please verify if this should be COVID-19 as positive results received' (Site from CRA).		17 Nov 2020 15:09:52
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:04:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:04:36
Data point term sent to Coder	System	12 Nov 2020 22:04:03
User entered 'covid-like illness'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 21:52:59
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Please reconcile as per protocol an illness visit is an MAAE' (Site from CRA).	(b) (4)	18 Nov 2020 19:06:19
Query 'Please reconcile as per protocol an illness visit is an MAAE' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:00:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:59:49
User opened query 'Please reconcile as per protocol an illness visit is an MAAE' (Site from CRA).	(b) (4)	17 Nov 2020 15:10:13
User entered 'No (N)'	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:52:54
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:52:53
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Please reconcile as subject symptom log notes subject is symptomatic and there are positive illness COVID results' (Site from CRA).	(b) (4)	18 Nov 2020 19:06:20
Query 'Please reconcile as subject symptom log notes subject is symptomatic and there are positive illness COVID results' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:00:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:59:49
User opened query 'Please reconcile as subject symptom log notes subject is symptomatic and there are positive illness COVID results' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:10:45
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:49:58
User closed query 'Re-query: CRA error in last query Per symptoms start date is to be recorded in EDC and source as 09Nov2020' (Site from CRA).		24 Nov 2020 21:49:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Query 'Re-query: CRA error in last query. Per symptoms start date is to be recorded in EDC and source as 09Nov2020' answered with 'DATA UPDATED' (Site from CRA).	(b) (4) Russell Herstein (b) (4)	24 Nov 2020 19:41:04
User entered '9 Nov 2020' reason for change: Data Entry Error	Russell Herstein (b) (4)	24 Nov 2020 19:40:54
User opened query 'Re-query: CRA error in last query. Per symptoms start date is to be recorded in EDC and source as 09Nov2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:10:46
User closed query 'Per the source start date documented as 13NO2020 please update to refelct the source' (Site from CRA).		24 Nov 2020 03:10:46
Query 'Per the source start date documented as 13NO2020 please update to refelct the source' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4)	23 Nov 2020 22:52:26
Signature has been broken.	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 22:52:17
User entered '13 Nov 2020' reason for change: Data Entry Error	Russell Herstein (b) (4)	23 Nov 2020 22:52:17
User opened query 'Per the source start date documented as 13NO2020 please update to refelct the source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:52:39
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '09 Nov 2020'	(b) (4) Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:53:09
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:53:18
DataPoint Un-verified.		23 Nov 2020 21:53:14
DataPoint Verified.		23 Nov 2020 21:53:12
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	18 Nov 2020 15:46:34
User entered 'No (N)' reason for change: Data Entry Error	System	18 Nov 2020 15:46:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Linden DeBoer (b) (4)	18 Nov 2020 15:46:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 15:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 15:44:31
User entered 'Yes (Y)' reason for change: Data Entry Error	System	18 Nov 2020 15:38:04
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:38:04
User entered empty.	System	13 Nov 2020 15:38:04
User entered 'Yes (Y)' reason for change: Data Entry Error	System	13 Nov 2020 15:38:04
User opened query 'Data is required. Please complete.' (Site from System).	Linden DeBoer (b) (4)	13 Nov 2020 15:38:04
User entered empty.	(b) (4)	13 Nov 2020 15:38:04
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:03:06
User entered empty.	System	12 Nov 2020 22:03:06
User entered empty.	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:53:16
User closed query 'End date is after date of death. Please update as appropriate.' (Site from System). Signature has been broken.	System Linden DeBoer (b) (4)	20 Nov 2020 22:40:42
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	20 Nov 2020 22:40:42
User opened query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	20 Nov 2020 22:39:59
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4) System	18 Nov 2020 15:44:31
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 15:44:31
User entered '17 Nov 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	18 Nov 2020 15:44:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4) System	18 Nov 2020 15:44:02
User entered empty.	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:53:27
DataPoint Un-verified.		23 Nov 2020 21:53:24
DataPoint Verified.		23 Nov 2020 21:53:19
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:53:25
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	18 Nov 2020 15:44:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	13 Nov 2020 15:38:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:38:04
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	13 Nov 2020 15:38:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:03:06
User entered empty.	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 21:53:30
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	18 Nov 2020 15:44:02
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Nov 2020 15:38:04
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	13 Nov 2020 15:38:04
	(b) (4)	
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Nov 2020 22:03:06
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 21:53:34
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '1' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 15:44:02
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
DataPoint Un-verified.		23 Nov 2020 21:53:50
DataPoint Verified.		23 Nov 2020 21:53:44
DataPoint Un-verified.		23 Nov 2020 21:53:38
DataPoint Verified.		23 Nov 2020 21:53:36
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:55:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
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	13 Nov 2020 15:38:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	13 Nov 2020 15:38:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Nov 2020 22:03:06
	Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User closed query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:21:35
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:35
Query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	23 Nov 2020 16:57:55
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Nov 2020 16:57:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Nov 2020 16:57:49
User opened query 'Per CDM: AE started after first dose, yet Not Applicable is selected for Relationship to Study Procedure. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:33:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:38:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:38:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	13 Nov 2020 15:38:04
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:03:06
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User entered 'Not Applicable (NOT APPLICABLE)'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	25 Mar 2021 21:10:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:55:49
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06
	(b) (4)	

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:51
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per CDM re-query: AE outcome is recorded as fatal however the reason for death on End of study is recorded as 'Unknown'. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:32:04
Query 'Per CDM re-query: AE outcome is recorded as fatal however the reason for death on End of study is recorded as 'Unknown'. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	19 Jan 2021 23:45:31
User opened query 'Per CDM re-query: AE outcome is recorded as fatal however the reason for death on End of study is recorded as 'Unknown'. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 05:07:28
User closed query 'Per CDM: Please reconcile COVID-19 is the cause of death as End Of Study eCRF currently has "UNKNOW" listed as cause of death. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 05:00:15
Query 'Per CDM: Please reconcile COVID-19 is the cause of death as End Of Study eCRF currently has "UNKNOW" listed as cause of death. ' answered with 'Still awaiting medical records from hospital' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 16:44:42
User opened query 'Per CDM: Please reconcile COVID-19 is the cause of death as End Of Study eCRF currently has "UNKNOW" listed as cause of death. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 17:02:26
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:55:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:59
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	18 Nov 2020 15:44:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:56:06
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 21:11:23
Query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' answered with 'Subject was not hospitalized. Subject was DOA upon arrival at local ER' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	02 Feb 2021 23:55:25
User opened query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 15:48:34
User closed query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 20:31:45
Query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' answered with 'will update and send records once records are received from hospital' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	22 Jan 2021 21:16:10

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 19:10:56
User closed query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:30:49
Query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'will update when update is available. Records and autopsy results have been requested but not received' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:13:27
User opened query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:03:45
User closed query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 20:20:27
Query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	19 Jan 2021 23:45:54

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 11:10:26
User closed query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:43:41
Query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'will update once records are received' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:45:10
User opened query 'PVQuery: Please clarify if subject was hospitalized. If yes, please send a hospital discharge summary, medical records and autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 23:59:17
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:56:03
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System (b) (4)	18 Nov 2020 15:46:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 15:46:34
User entered 'SITE WAS MADE AWARE OF PATIENT BEING DECEASED BY LOCAL NEWSPAPER OBITUARY' reason for change: Data Entry Error	Linden DeBoer (b) (4)	18 Nov 2020 15:46:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 15:44:02

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 15:38:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 15:38:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Nov 2020 22:03:06
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	18 Nov 2020 15:44:02
User entered '0'	System	13 Nov 2020 15:38:04
User entered '1'	System	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	17 Nov 2020 21:59:49
User entered '0'	System	12 Nov 2020 22:03:06

US3032204

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:58:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:27:29

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:59:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 06:03:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 06:03:11
Data point term sent to Coder	System	14 Aug 2020 20:32:34
User entered 'Toprol'	Kelsey Kelley (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:59:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:01:59
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH condition that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 07:21:54
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH condition that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify. ' answered with 'ADDED TO MED HISTORY' (Site from DM).	Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:27:45
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH condition that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:27:55
User entered 'medical history: headaches'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:13
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:15
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:02:54
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'UN Jan 2019' reason for change: Data Entry Error	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	Russell Herstein (b) (4)	30 Sep 2020 18:27:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'un May 2019'	(b) (4), (b) (6)	16 Aug 2020 13:23:34
	System	14 Aug 2020 20:32:02
	Kelsey Kelley (b) (4)	14 Aug 2020 20:32:02
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:17
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:02
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'UN May 2019' reason for change:	(b) (4)	
Data Entry Error	Russell Herstein (b) (4)	30 Sep 2020 18:27:36
User entered 'un UNK 2020'	(b) (4)	
	Kelsey Kelley (b) (4)	14 Aug 2020 20:32:02
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:07
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	14 Aug 2020 20:32:02

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 00:22:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:36
Data point term sent to Coder	System	14 Aug 2020 20:33:36
User entered 'armour thyroid'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '240'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:23:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:32:47
User entered 'un Jan 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	14 Aug 2020 20:32:47

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 00:13:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 00:13:17
Data point term sent to Coder	System	14 Aug 2020 20:33:37
User entered 'atorvastatin'	Kelsey Kelley (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'medical history: hypercholesterolemia'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 07:31:41
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please update applicable details as appropriate or provide clarification. ' answered with 'data updated ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	30 Sep 2020 19:11:58
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH condition. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:25:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	16 Aug 2020 13:23:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:33:16
User entered 'un Jan 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	14 Aug 2020 20:33:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 20:17:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 20:17:45
Data point term sent to Coder	System	22 Sep 2020 20:17:21
Coding entries removed.	Kelsey Kelley (b) (4)	22 Sep 2020 20:17:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 00:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 00:13:38
Data point term sent to Coder	System	14 Aug 2020 20:34:38
User entered 'tresiba'	Kelsey Kelley (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. '(Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 09:24:51
Query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:17:28
User entered 'MEDICAL HISTORY: type 1 diabetes' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:17:13
User opened query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. '(Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:28:21
User entered 'medical history:'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '28'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'units'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per CDM Please note the start date of medication (UNMAR2019)does not match with start date of the indication in MH (1986).Kindly correct or clarify,' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 07:34:25
Query 'Per CDM Please note the start date of medication (UNMAR2019)does not match with start date of the indication in MH (1986).Kindly correct or clarify,' answered with 'CORRECT AS ENTERED. SUBJECT PRESCRIBED CURRENT MEDICATION IN MARCH/2019' (Site from DM).	Russell Herstein (b) (4) (b) (4)	30 Sep 2020 18:32:46
User opened query 'Per CDM Please note the start date of medication (UNMAR2019)does not match with start date of the indication in MH (1986).Kindly correct or clarify,' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:32:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		16 Aug 2020 13:23:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:33:56
User entered 'un Mar 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	14 Aug 2020 20:33:56

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: FIASP FLEXTOUCH - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 09:47:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 09:47:55
Data point term sent to Coder	System	04 Dec 2020 22:21:29
Coding entries removed.	Samantha Wieseler (b) (4)	04 Dec 2020 22:20:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: FIASP FLEXTOUCH - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 23:17:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Sep 2020 23:17:40
Data point term sent to Coder	System	22 Sep 2020 20:18:23
Coding entries removed.	Kelsey Kelley (b) (4)	22 Sep 2020 20:18:01

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: FIASP FLEXTOUCH - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	(b) (4) 04 Sep 2020 11:07:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	(b) (4) 04 Sep 2020 11:07:37
Data point term sent to Coder	System	14 Aug 2020 20:35:40
User entered 'fiasp flex touch'	Kelsey Kelley (b) (4)	(b) (4) 14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User closed query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. '(Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 09:25:08
Query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:18:14
User entered 'MEDICAL HISTORY: diabetes type 1' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	22 Sep 2020 20:18:01
User opened query 'Per DM CLR: Please review Indication and update to provide the actual MH condition that this medication was used for. Please update as appropriate or provide clarification. '(Site from DM).	(b) (4), (b) (6)	02 Sep 2020 06:25:55
User entered 'medical history:'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'unit per carb (sliding scale)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:20:44
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:20:44
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:20:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Kelsey Kelley (b) (4)	14 Aug 2020 20:35:30
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:23:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:35:30
User entered 'un Jun 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:28:51
Query 'Ongoing is marked as "NO" please update to reflect the source.' canceled (Site from CRA).		23 Nov 2020 22:28:49
User opened query 'Ongoing is marked as "NO" please update to reflect the source.' (Site from CRA).		23 Nov 2020 22:28:07
DataPoint Un-verified.		23 Nov 2020 22:25:59
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	14 Aug 2020 20:35:30
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:28:55
DataPoint Un-verified.		23 Nov 2020 22:28:42
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	14 Aug 2020 20:35:30

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 00:22:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 00:22:36
Data point term sent to Coder	System	14 Aug 2020 20:36:43
User entered 'armour thyroid'	Kelsey Kelley (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '180'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:23:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:36:18
User entered 'un Nov 2019'	Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:58:09
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	14 Aug 2020 20:36:18

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 22:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:40:36
Data point term sent to Coder	System	11 Nov 2020 22:24:41
User entered 'seasonal influenza vaccine'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'prophylaxis for seasonal influenza'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Nov 2020 22:33:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 22:33:23
User entered 'mL (mL)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Nov 2020 22:33:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Nov 2020 22:33:23
User entered empty.	System	11 Nov 2020 22:24:34
	Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34
	(b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '30 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '30 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:24:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 23:10:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 23:10:37
Data point term sent to Coder	System	11 Nov 2020 22:28:49
User entered 'aspirin'	Kelsey Kelley (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '325'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '09 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:47:58
DataPoint Verified.		3 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:28:36

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Nov 2020 06:10:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:10:38
Data point term sent to Coder	System	11 Nov 2020 22:29:52
User entered 'ondansetron'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '8'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:29:27

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	(b) (4) (b) (4) Coder Import (b) (4)	11 Nov 2020 23:13:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:13:38
Data point term sent to Coder	System	11 Nov 2020 22:30:53
User entered 'azithromycin'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '500'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	6 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	3 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	11 Nov 2020 22:30:28

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 04:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 04:34:42
Data point term sent to Coder	System	12 Nov 2020 22:00:59
User entered 'methylprednisolone'	Kelsey Kelley (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '24'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '10 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 05:00:41
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:23:42
DataPoint Un-verified.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:23:36
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:23:36
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:23:36
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. '(Site from DM).	(b) (4), (b) (6)	03 Dec 2020 09:51:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:00:34

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 04:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 04:34:43
Data point term sent to Coder	System	12 Nov 2020 22:02:00
User entered 'methylprednisolone'	Kelsey Kelley (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '11 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:01:22

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 04:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 04:34:43
Data point term sent to Coder	System	12 Nov 2020 22:03:02
User entered 'methylprednisolone'	Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '12 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '12 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	12 Nov 2020 22:02:09

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 19:57:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 19:57:47
Data point term sent to Coder	System	16 Nov 2020 19:57:25
Data point term sent to Coder	System	16 Nov 2020 19:56:24
User entered 'METHYLPREDNISOLONE'	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'COVID-LIKE ILLNESS'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:56:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:56:42
User entered '12' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:55:50
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:56:42
User entered 'mg (mg)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:56:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:56:42
User entered 'once (ONCE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:55:50
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:56:42
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:56:42
User entered '13 Nov 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:55:50
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:56:42
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:56:42
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:55:50
	Kelsey Kelley (b) (4)	16 Nov 2020 19:55:50
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:55:50

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 20:00:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 20:00:47
Data point term sent to Coder	System	16 Nov 2020 19:59:28
Data point term sent to Coder	System	16 Nov 2020 19:58:26
User entered 'METHYLPREDNISOLONE'	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'COVID-LIKE ILLNESS'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	16 Nov 2020 19:58:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:58:39
User entered '8' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	16 Nov 2020 19:58:10
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:58:39
User entered 'mg (mg)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:58:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:58:39
User entered 'once (ONCE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 19:58:10
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:58:39
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:58:39
User entered '14 Nov 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:58:10
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:58:39
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
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	16 Nov 2020 19:58:39
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Nov 2020 19:58:10
	Kelsey Kelley (b) (4)	16 Nov 2020 19:58:10
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:58:10

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 20:00:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 20:00:46
Data point term sent to Coder	System	16 Nov 2020 19:59:29
User entered 'METHYLPREDNISOLONE'	Kelsey Kelley (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'COVID-LIKE ILLNESS'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '4'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '15 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '15 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 19:59:16

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Nov 2020 01:54:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 01:54:50
Data point term sent to Coder	System	16 Nov 2020 20:40:27
User entered 'albuterol nebulizer'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'covid-like illness'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User closed query 'Per DM CLR-RQ: Please provide the actual dose for this medication instead of treatment count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		31 Jan 2021 10:11:09
Query 'Per DM CLR-RQ: Please provide the actual dose for this medication instead of treatment count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'dosage had been put originally and was told to change to 1 tx. please decide on what should be marked and update us. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	19 Jan 2021 23:47:00
User opened query 'Per DM CLR-RQ: Please provide the actual dose for this medication instead of treatment count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:40:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:48:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:02:23
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:24:50
DataPoint Un-verified.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:24:32
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:24:32
User entered '1' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	04 Dec 2020 22:24:32

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 09:51:50
User signature succeeded.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User entered '0.083'	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:39
	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:24:32
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:24:32
User entered 'treatment' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	04 Dec 2020 22:24:32
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:36:14
DataPoint Un-verified.		23 Nov 2020 22:36:09
DataPoint Verified.		23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '%'	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 20:39:33
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '14 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 01:24:19
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:23:02
DataPoint Un-verified.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:22:58
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:22:58
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:22:58
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:56:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:39
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
DataPoint Un-verified.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:22:58
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:22:58
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:22:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	16 Nov 2020 20:39:33
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:03:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered empty.	System	16 Nov 2020 20:39:33

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Dec 2020 17:44:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:44:00
Data point term sent to Coder	System	04 Dec 2020 22:26:31
User entered 'Azithromycin'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38
	(b) (4)	

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'No (N)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'Covid Like illness'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered '250'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'mg (mg)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered empty.	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'once daily (QD)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered empty.	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered '11 Nov 2020'	(b) (4) Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered '0'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'No (N)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered '14 Nov 2020'	(b) (4) Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'No (N)'	Samantha Wieseler (b) (4)	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '1'	System	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:51:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '804 (804)'	System	04 Dec 2020 22:25:38

US3032204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:51:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 00:59:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:34:16
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Aug 2020 20:27:22

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered '16 Nov 2020'	(b) (4) Linden DeBoer (b) (4)	20 Nov 2020 22:39:59
	(b) (4)	

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered 'Death (DEATH)'	(b) (4) Linden DeBoer (b) (4)	20 Nov 2020 22:39:59
	(b) (4)	

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered empty.	(b) (4) Linden DeBoer (b) (4)	20 Nov 2020 22:39:59
	(b) (4)	

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User closed query 'Per CDM Re-query: Site response on AE #1 indicates subject was DOA at local ER. Since this was 4 months ago, it's expected medical records from local ER have been received. Please confirm and verify if main cause of death is Covid-19. If yes, update 'If reason for discontinuation is Death, main cause of death' data-field as appropriate. Death caused by Covid-19 is one of the Long-term end points of this study. Per page 76 of Protocol Amendment 7, "Death attributed to Covid-19 is defined as any participant who dies during the study with a cause directly attributed to a complication of Covid-19". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 10:43:07
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	25 Mar 2021 21:11:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	25 Mar 2021 20:40:30
Query 'Per CDM Re-query: Site response on AE #1 indicates subject was DOA at local ER. Since this was 4 months ago, it's expected medical records from local ER have been received. Please confirm and verify if main cause of death is Covid-19. If yes, update 'If reason for discontinuation is Death, main cause of death' data-field as appropriate. Death caused by Covid-19 is one of the Long-term end points of this study. Per page 76 of Protocol Amendment 7, "Death attributed to Covid-19 is defined as any participant who dies during the study with a cause directly attributed to a complication of Covid-19". ' answered with 'we have a call out to the family for death certificate as no autopsy was performed therefore cause of death was "unknown" until subjects wife said it was COVID related' (Site from DM).	Linden DeBoer (b) (4)	22 Mar 2021 21:35:19
DataPoint Un-verified.	Linden DeBoer (b) (4)	22 Mar 2021 21:34:05
Signature has been broken.	Linden DeBoer (b) (4)	22 Mar 2021 21:34:05

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered 'Adverse event (ADVERSE EVENT) reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:34:05
User opened query 'Per CDM Re-query: Site response on AE #1 indicates subject was DOA at local ER. Since this was 4 months ago, it's expected medical records from local ER have been received. Please confirm and verify if main cause of death is Covid-19. If yes, update 'If reason for discontinuation is Death, main cause of death' data-field as appropriate. Death caused by Covid-19 is one of the Long-term end points of this study. Per page 76 of Protocol Amendment 7, "Death attributed to Covid-19 is defined as any participant who dies during the study with a cause directly attributed to a complication of Covid-19". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:54:12
User closed query 'Per DM re-query: Per previous response kindly update keep the query in open state till the main cause of death is reported on this page.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:54:12
Query 'Per DM re-query: Per previous response kindly update keep the query in open state till the main cause of death is reported on this page.' answered with 'subjects wife did not have an autopsy done. therefore this page will continually remain as unknown. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:03:35
User opened query 'Per DM re-query: Per previous response kindly update keep the query in open state till the main cause of death is reported on this page.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:05:31
User closed query 'Per CDM: Please note that the Outcome of AE #1 is recorded as Fatal, yet the main cause of death is 'Unknown' on this page. Please review, reconcile and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:03:38
Query 'Per CDM: Please note that the Outcome of AE #1 is recorded as Fatal, yet the main cause of death is 'Unknown' on this page. Please review, reconcile and update this field as appropriate, else clarify. ' answered with 'will update once autopsy report is received' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	01 Feb 2021 22:29:52

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that the Outcome of AE #1 is recorded as Fatal, yet the main cause of death is 'Unknown' on this page. Please review, reconcile and update this field as appropriate, else clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 09:39:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 21:53:54
User entered 'Unknown (UNKNOWN)'	Linden DeBoer (b) (4)	24 Nov 2020 20:28:46
	(b) (4)	20 Nov 2020 22:39:59

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	Samantha Wieseler (b) (4)	25 Mar 2021 21:11:03
Signature has been broken.	(b) (4)	
User entered 'Immediate Cause is Cerebral Hypoperfusion due to Hypotension due to Asytole.'	Samantha Wieseler (b) (4)	25 Mar 2021 20:40:30
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	20 Nov 2020 22:39:59
	(b) (4)	

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered '16 Nov 2020'	(b) (4) Linden DeBoer (b) (4)	20 Nov 2020 22:39:59

US3032204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:53

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User closed query 'Per CDM: 'Was autopsy performed?' = 'Unknown', however, per site response on this form, subject's wife reported no autopsy was performed. Please update 'Was autopsy performed?' to 'No', else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 00:54:53
Query 'Per CDM: 'Was autopsy performed?' = 'Unknown', however, per site response on this form, subject's wife reported no autopsy was performed. Please update 'Was autopsy performed?' to 'No', else clarify. ' answered with 'updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:34:30
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:34:05
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:34:05
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:34:05
User opened query 'Per CDM: 'Was autopsy performed?' = 'Unknown', however, per site response on this form, subject's wife reported no autopsy was performed. Please update 'Was autopsy performed?' to 'No', else clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 16:00:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	24 Nov 2020 20:28:46
User entered 'Unknown (UNK)'	Linden DeBoer (b) (4) (b) (4)	20 Nov 2020 22:39:59

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '1'	(b) (4)	
	System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '1'	(b) (4)	
	System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '18/Nov/2020 13:46'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 13:29:00
User entered '1'	(b) (4)	
	System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		24 Nov 2020 21:53:29
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered '24/Nov/2020 13:28'	(b) (4) System	24 Nov 2020 13:29:00

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
Reviewed for Safety.		25 Nov 2020 15:12:38
DataPoint Verified.		24 Nov 2020 21:53:29
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:29:00

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 13:29:00
User entered '1'	(b) (4)	
	System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		16 Dec 2020 14:49:12
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered '25/Nov/2020 15:12'	(b) (4) System	25 Nov 2020 15:12:48

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
Reviewed for Safety.		03 Feb 2021 21:12:15
DataPoint Verified.		16 Dec 2020 14:49:12
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:12:48

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.	(b) (4)	24 Nov 2020 13:28:52
DataPoint Verified.	(b) (4)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	03 Feb 2021 21:12:28
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	25 Nov 2020 15:12:48
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	24 Nov 2020 13:29:00
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered '1'	(b) (4)	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:51:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
User entered '03/Feb/2021 16:12'	(b) (4) System	03 Feb 2021 21:12:28

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:51:53

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 19:47:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:51:17
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:12:28

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'USA-US032-2020-MRNA-1273-P301000012'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Yes (Y)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'No (N)'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Keith'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:46:34
User entered 'Vrbicky'	System	18 Nov 2020 18:46:17

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
Reviewed for Safety.		24 Nov 2020 13:28:52
DataPoint Verified.		23 Nov 2020 21:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:59
User entered 'US'	(b) (4) System	18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User entered '5'	System	23 Mar 2021 14:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:56
Signature has been broken.	(b) (4)	
User entered '4'	System	03 Feb 2021 21:12:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:48:07
Signature has been broken.	(b) (4)	
User entered '3'	System	25 Nov 2020 15:12:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:46
Signature has been broken.	(b) (4)	
User entered '2'	System	24 Nov 2020 13:29:00
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 13:29:00
User entered '1'	(b) (4)	
	System	20 Nov 2020 16:29:59
		18 Nov 2020 18:46:43

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:51:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User entered '23/Mar/2021 09:51'	(b) (4) System	23 Mar 2021 14:51:32

US3032204

Folder: SAE USA-US032-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

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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 19:47:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:38:49
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:51:32