

US3042192 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:57:30

All time stamps listed in this document are displayed in GMT

US3042192

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

[Participant ID](#)

US3042192

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

US3042192

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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	SCRN

US3042192

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3042192

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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

US3042192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3042192

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Were any significant conditions reported?

Yes ☒

No ☐

US3042192

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042192

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042192

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042192

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:19 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 07:19
Height (<i>xxx.x</i>)	188.0 cm
Weight (<i>xxx.x</i>)	98.0 kg
BMI (<i>xxx.x</i>)	27.72748 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042192

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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.

US3042192

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 10:00:58

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3042192

Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3042192

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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

What was the participant's randomization number? 104163

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 ☒

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Height	ND - Not Done
Weight	ND - Not Done

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	07:19 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 07:19
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 09:00
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3042192

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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.

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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) 08:21 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 08:21

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

US3042192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

07:40 (24 HR)

Collection date and time (derived)

14 AUG 2020 07:40

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:33	14 AUG 2020 07:33
Nasopharyngeal Swab 2	No		

US3042192

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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 08:57

PC Open Date & Time

14 AUG 2020 08:41

PC Close Date & Time

14 AUG 2020 11:11

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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 97.9 °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 22:55
PC Open Date & Time	14 AUG 2020 12:06
PC Close Date & Time	15 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☒

No ☐

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

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 AUG 2020 12:21

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	16 AUG 2020 12:04
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

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

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

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

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

19 AUG 2020 14:15

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

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

97.1 °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

20 AUG 2020 23:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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 08:58

PC Open Date & Time

14 AUG 2020 08:41

PC Close Date & Time

14 AUG 2020 11:11

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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 22:56

PC Open Date & Time

14 AUG 2020 12:06

PC Close Date & Time

15 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

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 12:22

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:04

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:01

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 14:15

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 23:15

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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 ☐

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 08:59
PC Open Date & Time	14 AUG 2020 08:41
PC Close Date & Time	14 AUG 2020 11:11

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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 ☐

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 22:57
PC Open Date & Time	14 AUG 2020 12:06
PC Close Date & Time	15 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

44 of 731

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	15 AUG 2020 12:23
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

46 of 731

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	16 AUG 2020 12:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

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 ☒

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	17 AUG 2020 12:01
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

50 of 731

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	18 AUG 2020 12:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 731

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	19 AUG 2020 14:15
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 731

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

Yes ☐	
PC Time stamp	20 AUG 2020 23:15
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042192

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042192

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3042192

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:17
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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.

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

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

PARTICIPANTS LAB VALUES ARE STILL ELEVATED. DID NOT WANT TO PARTICIPATE ANY FURTHER IN THE STUDY.

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3042192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3042192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:00:58

Generated On: 09 Jun 2021 14:57:30

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3042192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:57:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3042192

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3042192

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:57:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3042192

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3042192

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:30

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

US3042192

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3042192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:30

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection Date and Time (derived)

US3042192

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

AEID

Adverse event

ELEVATED LIVER ENZYMES

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

84 of 731

EAB) (1725)

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

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

Yes ☒

No ☐

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

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

87 of 731

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

	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)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 17

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)

89 of 731

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

	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)	UN UNK 1985	
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	☐

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

91 of 731

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

	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)	UN UNK	1985
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	☒

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SOLICITED SYMPTOMS-BODY
AND JOINT ACES

Dose per administration 800

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)

93 of 731

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:00:13

Generated On: 09 Jun 2021 14:57:30

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	21 AUG 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3042192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3042192

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Date of dosing discontinuation (dd MMM yyyy) 14 SEP 2020

Primary reason for dosing discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 10:00:57

Generated On: 09 Jun 2021 14:57:30

Date of study discontinuation/completion (dd MMM yyyy) 14 SEP 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 AE #1

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3042192 (Prod: Meridian Clinical Research)

US3042192

Form: Participant Creation

Generated On: 09 Jun 2021 14:57:30

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'US3042192'	RWS_ENDPOINT	14 Aug 2020 12:49:25
	ENDPOINT (b) (4)	
	(b) (4)	

US3042192

Form: Participant Creation

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:19

US3042192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:01:42
	(b) (4)	

US3042192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:26

US3042192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	15 Aug 2020 13:01:42
	(b) (4)	

US3042192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'SCRN'	(b) (4), (b) (6) System	15 Aug 2020 13:01:42

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered (b) (6) 1980'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:27

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '40'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'YEARS'	(b) (4), (b) (6) System	15 Aug 2020 13:03:55

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '40'	(b) (4), (b) (6) System	14 Aug 2020 13:43:52

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Male (M)'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '1'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:03:55

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:03:55
	(b) (4)	

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 13:43:52

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'Aug 2020'	(b) (4), (b) (6) System	14 Aug 2020 13:43:52

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 13:43:52

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Amendment 2 (2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 13:43:52

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 13:43:52
	(b) (4)	

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 13:43:52
	(b) (4)	

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 13:43:52
	(b) (4)	

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Aug 2020 13:43:52
	(b) (4)	

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:26

US3042192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '1'	(b) (4), (b) (6) System	14 Aug 2020 13:43:54

US3042192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 13:43:54
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:57:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:02

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:34:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:34:08
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 20:14:16
Coding entries removed.	Rylea Gulick (b) (4)	16 Oct 2020 20:13:25
	(b) (4)	
User entered 'MILD ASTHMA' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 20:13:25
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 13:05:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 13:05:24
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:04:41
User entered 'ASTHMA'	Rylea Gulick (b) (4)	15 Aug 2020 13:04:18
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'UN UNK 1985'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:04:18
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:04:18
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'Jan 1985'	(b) (4), (b) (6) System	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '1985'	(b) (4), (b) (6) System	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:18

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
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)	15 Aug 2020 13:05:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 13:05:23
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:04:41
User entered 'HYPOTHYROIDISM'	Rylea Gulick (b) (4)	15 Aug 2020 13:04:31
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:04:31
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:04:31
	(b) (4)	

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:31

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Aug 2020 13:05:24
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 13:05:24
Data point term sent to Coder	System	15 Aug 2020 13:04:42
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'UN UNK 1985'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'Jan 1985'	(b) (4), (b) (6) System	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '1985'	(b) (4), (b) (6) System	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:04:40

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '07:19'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 07:19'	(b) (4), (b) (6) System	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '188.0' cm	(b) (4) Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
DataPoint set to visible.	(b) (4) System	14 Aug 2020 13:43:54

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '98.0' kg	(b) (4) Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
DataPoint set to visible.	(b) (4) System	14 Aug 2020 13:43:54

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
Amendment Manager: User entered '27.72748'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:56:42
User entered '27.7'	System	15 Aug 2020 13:05:01
DataPoint set to visible.	System	14 Aug 2020 13:43:54

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'kg/m2'	(b) (4), (b) (6)	
	System	15 Aug 2020 13:05:01
DataPoint set to visible.	System	14 Aug 2020 13:43:54

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
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)	09 Oct 2020 06:56:58
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 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:16:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:16:48
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)	08 Oct 2020 08:11:04
User entered '36.9' C	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:16:48
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:16:48
change Data Entry Error	(b) (4)	
User entered '78'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:16:48
change Data Entry Error	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:16:48
change Data Entry Error	(b) (4)	
User entered '133'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:16:48
change Data Entry Error	(b) (4)	
User entered '78'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:01
	(b) (4)	

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:05:01

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:37:35

US3042192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 03:37:35

US3042192

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 15:58:21
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:07
	(b) (4)	

US3042192

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 15:58:21
User entered empty; reason for change Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 15:58:21
	(b) (4)	
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 21:15:19
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:07
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '1'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:30

US3042192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:05:30
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:43

US3042192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:43
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:43
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'VISIT1'	(b) (4), (b) (6) System	15 Aug 2020 13:05:43

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:34

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:26:08
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:26:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 12:49:34
User entered '104163' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:34

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 12:49:34

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:51

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:51
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:51

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:05:51
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:05:51

US3042192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:30

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	16 Oct 2020 20:13:41
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:13:15

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 03:53:27
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	27 Oct 2020 14:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	27 Oct 2020 14:38:53
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:33:38
User entered '188.0' cm	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	27 Oct 2020 14:38:53
change Data Entry Error	(b) (4)	
User entered '98.0' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 03:53:27
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	27 Oct 2020 14:38:55
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	27 Oct 2020 14:38:53
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:33:38
User entered '188.0' cm	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	27 Oct 2020 14:38:53
change Data Entry Error	(b) (4)	
User entered '98.0' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '07:19'	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 07:19'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '78'	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '133'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '78'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 03:53:27
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	27 Oct 2020 14:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	27 Oct 2020 14:38:53
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:33:38
User entered '188.0' cm	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	27 Oct 2020 14:38:53
change Data Entry Error	(b) (4)	
User entered '98.0' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
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 07:27:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:57
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).		15 Aug 2020 13:06:36
User entered '09:00'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 09:00'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:06:36
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '63'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '124'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '74'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:06:36

US3042192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:03

US3042192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:03

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 13:44:10
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 13:44:10
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '08:21'	Rylea Gulick (b) (4)	14 Aug 2020 13:44:10
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 08:21'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'ONCE'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:12

US3042192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:12

US3042192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '07:40'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:12
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 07:40'	(b) (4), (b) (6) System	15 Aug 2020 13:07:12

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:28
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:28

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:28
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '07:33'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:28
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '14 Aug 2020 07:33'	(b) (4), (b) (6) System	15 Aug 2020 13:07:28

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:07:28

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:28
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:07:28
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:07:28

US3042192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:30
	(b) (4)	

US3042192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 13:07:30

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:56:48', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '532e0c35-ecd8-4d82-a447-b2653d84498e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Aug 2020 13:57:19
	System	14 Aug 2020 13:57:19

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:56:53', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '532e0c35-ecd8-4d82-a447-b2653d84498e' User entered '98.0'	(b) (4), (b) (6) System	14 Aug 2020 13:57:19
	System	14 Aug 2020 13:57:19

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:57:07', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '532e0c35-ecd8-4d82-a447-b2653d84498e' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 13:57:19
	System	14 Aug 2020 13:57:19

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:57:17', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '532e0c35-ecd8-4d82-a447-b2653d84498e' User entered '14 Aug 2020 08:57'	(b) (4), (b) (6) System	14 Aug 2020 13:57:19
	System	14 Aug 2020 13:57:19

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 08:41'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 11:11'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:02', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'd5cc6e2a-c503-4515-aab9-d1da8fd09e8d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 03:55:24
	System	15 Aug 2020 03:55:24

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'd5cc6e2a-c503-4515-aab9-d1da8fd09e8d' User entered '97.9'	(b) (4), (b) (6) System	15 Aug 2020 03:55:24
	System	15 Aug 2020 03:55:24

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:15', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'd5cc6e2a-c503-4515-aab9-d1da8fd09e8d' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 03:55:24
	System	15 Aug 2020 03:55:24

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:19', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'd5cc6e2a-c503-4515-aab9-d1da8fd09e8d' User entered '14 Aug 2020 22:55'	(b) (4), (b) (6) System	15 Aug 2020 03:55:24
	System	15 Aug 2020 03:55:24

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 12:06'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 2'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:20:59', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 17:21:52
	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:03', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94' User entered '98.8'	(b) (4), (b) (6) System	15 Aug 2020 17:21:52
	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:26', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'IBUPROFEN WAS TAKEN' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:59:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 23:47:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94'	System	15 Aug 2020 17:21:52
User entered '1'	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94' User entered '0'	(b) (4), (b) (6) System	15 Aug 2020 17:21:52
	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:50', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '40163b11-392b-42ef-b6b5-bf19ab3e2a94' User entered '15 Aug 2020 12:21'	(b) (4), (b) (6) System	15 Aug 2020 17:21:52
	System	15 Aug 2020 17:21:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 3'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:20', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 17:04:42
	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:26', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa' User entered '99.3'	(b) (4), (b) (6) System	16 Aug 2020 17:04:42
	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:33', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 17:04:42
	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'IBUPROFEN WAS TAKEN' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 13:59:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 23:47:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa'	System	16 Aug 2020 17:04:42
User entered '1'	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa' User entered '0'	(b) (4), (b) (6) System	16 Aug 2020 17:04:42
	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:41', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'fa8f3b7a-53a9-426f-8211-544a5b2d3dfa' User entered '16 Aug 2020 12:04'	(b) (4), (b) (6) System	16 Aug 2020 17:04:42
	System	16 Aug 2020 17:04:42

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 4'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:32', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Aug 2020 17:00:52
	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:37', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5' User entered '98.8'	(b) (4), (b) (6) System	17 Aug 2020 17:00:52
	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:43', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Aug 2020 17:00:52
	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'IBUPROFEN WAS TAKEN' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:00:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 23:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5'	System	17 Aug 2020 17:00:52
User entered '1'	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5' User entered '0'	(b) (4), (b) (6) System	17 Aug 2020 17:00:52
	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:50', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '044b654a-3183-4bd7-910a-d800348f6bc5' User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	17 Aug 2020 17:00:52
	System	17 Aug 2020 17:00:52

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 5'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:01', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '575ad928-ee0b-4ce9-a0ac-f9020fbc758a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:13
	System	18 Aug 2020 17:56:13

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:05', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '575ad928-ee0b-4ce9-a0ac-f9020fbc758a' User entered '98.8'	(b) (4), (b) (6) System	18 Aug 2020 17:56:13
	System	18 Aug 2020 17:56:13

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:08', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '575ad928-ee0b-4ce9-a0ac-f9020fbc758a' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:13
	System	18 Aug 2020 17:56:13

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '575ad928-ee0b-4ce9-a0ac-f9020fbc758a' User entered '18 Aug 2020 12:56'	(b) (4), (b) (6) System	18 Aug 2020 17:56:13
	System	18 Aug 2020 17:56:13

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 6'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:07', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4ce78434-4c58-488d-8b46-fd43098ffdfc' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:21
	System	19 Aug 2020 19:15:21

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4ce78434-4c58-488d-8b46-fd43098ffdfc' User entered '97.1'	(b) (4), (b) (6) System	19 Aug 2020 19:15:21
	System	19 Aug 2020 19:15:21

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:14', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4ce78434-4c58-488d-8b46-fd43098ffdfc' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:21
	System	19 Aug 2020 19:15:21

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:18', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4ce78434-4c58-488d-8b46-fd43098ffdfc' User entered '19 Aug 2020 14:15'	(b) (4), (b) (6) System	19 Aug 2020 19:15:21
	System	19 Aug 2020 19:15:21

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 7'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:34', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4c41e244-afad-4096-9ec9-709bd41687d2' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 04:14:45
	System	21 Aug 2020 04:14:45

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4c41e244-afad-4096-9ec9-709bd41687d2' User entered '97.1'	(b) (4), (b) (6) System	21 Aug 2020 04:14:45
	System	21 Aug 2020 04:14:45

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:41', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4c41e244-afad-4096-9ec9-709bd41687d2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 04:14:45

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:43', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '4c41e244-afad-4096-9ec9-709bd41687d2' User entered '20 Aug 2020 23:14'	(b) (4), (b) (6) System	21 Aug 2020 04:14:45
	System	21 Aug 2020 04:14:45

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:58:04', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '99b6bcd6-cd4d-47f0-a1a8-929371b5794f' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 13:58:50
	System	14 Aug 2020 13:58:50

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:58:31', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '99b6bcd6-cd4d-47f0-a1a8-929371b5794f' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 13:58:50
	System	14 Aug 2020 13:58:50

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:58:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '99b6bcd6-cd4d-47f0-a1a8-929371b5794f' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 13:58:50
	System	14 Aug 2020 13:58:50

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:58:45', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '99b6bcd6-cd4d-47f0-a1a8-929371b5794f' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 13:58:50
	System	14 Aug 2020 13:58:50

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:58:49', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '99b6bcd6-cd4d-47f0-a1a8-929371b5794f' User entered '14 Aug 2020 08:58'	(b) (4), (b) (6) System	14 Aug 2020 13:58:50
	System	14 Aug 2020 13:58:50

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 08:41'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 11:11'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:29', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '13dd25e8-600e-453f-94c0-ee563c74a5dc' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	15 Aug 2020 03:56:29
	System	15 Aug 2020 03:56:29

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:55:44', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '13dd25e8-600e-453f-94c0-ee563c74a5dc' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 03:56:29
	System	15 Aug 2020 03:56:29

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:15', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '13dd25e8-600e-453f-94c0-ee563c74a5dc' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 03:56:29
	System	15 Aug 2020 03:56:29

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:25', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '13dd25e8-600e-453f-94c0-ee563c74a5dc' User entered 'None (1)'	(b) (4), (b) (6) System	15 Aug 2020 03:56:29
	System	15 Aug 2020 03:56:29

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:27', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '13dd25e8-600e-453f-94c0-ee563c74a5dc' User entered '14 Aug 2020 22:56'	(b) (4), (b) (6) System	15 Aug 2020 03:56:29
	System	15 Aug 2020 03:56:29

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 12:06'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 2'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:21:55', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'c61a9231-da0f-46d9-946f-c588cbc64796'	(b) (4), (b) (6)	15 Aug 2020 17:22:35
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 17:22:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:03', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'c61a9231-da0f-46d9-946f-c588cbc64796' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:22:35
	System	15 Aug 2020 17:22:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:28', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'c61a9231-da0f-46d9-946f-c588cbc64796' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:22:35
	System	15 Aug 2020 17:22:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:31', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'c61a9231-da0f-46d9-946f-c588cbc64796'	(b) (4), (b) (6)	
	System	15 Aug 2020 17:22:35
User entered 'None (1)'	System	15 Aug 2020 17:22:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:34', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'c61a9231-da0f-46d9-946f-c588cbc64796' User entered '15 Aug 2020 12:22'	(b) (4), (b) (6) System	15 Aug 2020 17:22:35
	System	15 Aug 2020 17:22:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 3'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:44', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bdf48a26-b5d8-45dc-b9b0-c0f76ee28c07'	(b) (4), (b) (6)	
	System	16 Aug 2020 17:04:55
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:04:55

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:45', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bdf48a26-b5d8-45dc-b9b0-c0f76ee28c07' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 17:04:55
	System	16 Aug 2020 17:04:55

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bdf48a26-b5d8-45dc-b9b0-c0f76ee28c07' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 17:04:55
	System	16 Aug 2020 17:04:55

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:50', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bdf48a26-b5d8-45dc-b9b0-c0f76ee28c07' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 17:04:55
	System	16 Aug 2020 17:04:55

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:53', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bdf48a26-b5d8-45dc-b9b0-c0f76ee28c07' User entered '16 Aug 2020 12:04'	(b) (4), (b) (6) System	16 Aug 2020 17:04:55
	System	16 Aug 2020 17:04:55

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 4'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:00:56', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '6bb408b0-4f29-47b8-a717-bb825ddabe8a' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:19
	System	17 Aug 2020 17:01:19

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:03', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '6bb408b0-4f29-47b8-a717-bb825ddabe8a' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:19
	System	17 Aug 2020 17:01:19

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '6bb408b0-4f29-47b8-a717-bb825ddabe8a' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:19
	System	17 Aug 2020 17:01:19

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:13', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '6bb408b0-4f29-47b8-a717-bb825ddabe8a' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:19
	System	17 Aug 2020 17:01:19

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:15', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '6bb408b0-4f29-47b8-a717-bb825ddabe8a' User entered '17 Aug 2020 12:01'	(b) (4), (b) (6) System	17 Aug 2020 17:01:19
	System	17 Aug 2020 17:01:19

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 5'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:14', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '425a98cd-782d-4086-818e-6c8c16086ce2' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:23
	System	18 Aug 2020 17:56:23

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:16', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '425a98cd-782d-4086-818e-6c8c16086ce2' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:23
	System	18 Aug 2020 17:56:23

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:17', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '425a98cd-782d-4086-818e-6c8c16086ce2' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:23
	System	18 Aug 2020 17:56:23

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:18', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '425a98cd-782d-4086-818e-6c8c16086ce2' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:23
	System	18 Aug 2020 17:56:23

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:21', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '425a98cd-782d-4086-818e-6c8c16086ce2' User entered '18 Aug 2020 12:56'	(b) (4), (b) (6) System	18 Aug 2020 17:56:23
	System	18 Aug 2020 17:56:23

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 6'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:22', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'f8f17cf2-8f6e-4184-bb62-efc47e14ccb7'	(b) (4), (b) (6)	
	System	19 Aug 2020 19:15:35
User entered 'None (1)'	System	19 Aug 2020 19:15:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:25', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'f8f17cf2-8f6e-4184-bb62-efc47e14ccb7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 19:15:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:26', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'f8f17cf2-8f6e-4184-bb62-efc47e14ccb7' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:35
	System	19 Aug 2020 19:15:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:29', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'f8f17cf2-8f6e-4184-bb62-efc47e14ccb7'	(b) (4), (b) (6) System	19 Aug 2020 19:15:35
User entered 'None (1)'	System	19 Aug 2020 19:15:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:31', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'f8f17cf2-8f6e-4184-bb62-efc47e14ccb7' User entered '19 Aug 2020 14:15'	(b) (4), (b) (6) System	19 Aug 2020 19:15:35
	System	19 Aug 2020 19:15:35

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 7'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:48', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '987b0589-c0fc-455c-9631-874a9048e3e5' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:07
	System	21 Aug 2020 04:15:07

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:50', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '987b0589-c0fc-455c-9631-874a9048e3e5' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:07
	System	21 Aug 2020 04:15:07

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:52', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '987b0589-c0fc-455c-9631-874a9048e3e5' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:07
	System	21 Aug 2020 04:15:07

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:14:55', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '987b0589-c0fc-455c-9631-874a9048e3e5' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:07
	System	21 Aug 2020 04:15:07

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:05', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '987b0589-c0fc-455c-9631-874a9048e3e5' User entered '20 Aug 2020 23:15'	(b) (4), (b) (6) System	21 Aug 2020 04:15:07
	System	21 Aug 2020 04:15:07

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:03', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:12', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:24', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:28', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:35', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:37', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:42', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T08:59:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '5c4eb5cf-51ca-4353-a533-eeca6580806e' User entered '14 Aug 2020 08:59'	(b) (4), (b) (6) System	14 Aug 2020 13:59:48
	System	14 Aug 2020 13:59:48

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 08:41'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 11:11'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:34', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:39', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:56:47', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:57:05', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:57:10', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:57:12', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:57:21', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-14T22:57:25', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '590c9c48-12c1-4696-8b74-3cfc32a8055e' User entered '14 Aug 2020 22:57'	(b) (4), (b) (6) System	15 Aug 2020 03:57:29
	System	15 Aug 2020 03:57:29

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '14 Aug 2020 12:06'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 2'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:40', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:46', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:22:58', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:23:07', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:23:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:23:19', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:23:22', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-15T12:23:24', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'ebb60cce-e87e-46df-91a9-41f9fc42a9f5' User entered '15 Aug 2020 12:23'	(b) (4), (b) (6) System	15 Aug 2020 17:23:27
	System	15 Aug 2020 17:23:27

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 3'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:04:57', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:01', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:04', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14'	(b) (4), (b) (6)	
	System	16 Aug 2020 17:05:20
User entered 'No interference with activity (1)'	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:10', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:12', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:15', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-16T12:05:17', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'daf44ddf-4a71-4403-b584-7471aa890a14' User entered '16 Aug 2020 12:05'	(b) (4), (b) (6) System	16 Aug 2020 17:05:20
	System	16 Aug 2020 17:05:20

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 4'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:20', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:24', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:26', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:32', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87'	(b) (4), (b) (6)	
	System	17 Aug 2020 17:01:49
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:36', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:41', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-17T12:01:43', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'dbdb439f-1617-4aeb-9a38-55c065047b87' User entered '17 Aug 2020 12:01'	(b) (4), (b) (6) System	17 Aug 2020 17:01:49
	System	17 Aug 2020 17:01:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 5'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:23', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:25', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:27', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:34', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:35', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:36', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-18T12:56:40', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '0a0e0f23-8c8e-4c53-ad10-4f9b389f773f' User entered '18 Aug 2020 12:56'	(b) (4), (b) (6) System	18 Aug 2020 17:56:42
	System	18 Aug 2020 17:56:42

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 6'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:35', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:37', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:38', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:39', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:40', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:41', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:43', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-19T14:15:45', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: 'bcfd5a61-27a9-413c-98fc-8eab886fe864' User entered '19 Aug 2020 14:15'	(b) (4), (b) (6) System	19 Aug 2020 19:15:49
	System	19 Aug 2020 19:15:49

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 13:44:10
User entered 'Day 7'	System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:11', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:16', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:19', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:21', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:25', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:26', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

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)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:29', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48281692-6554-413B-BA74-4C1849CE9DD0)', Time: '2020-08-20T23:15:31', User OID: 'PatientReportedOutcome (US3042192)', ODM File OID: '29e03581-394c-4bca-9d7f-4ec2dbe601ba' User entered '20 Aug 2020 23:15'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33
	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 13:44:10

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 8'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 9'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 8'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 9'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 8'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

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) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 04:15:33
User entered 'Day 9'	System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

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) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:52:30

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:57:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:52:30
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 04:15:33

US3042192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:51:35

US3042192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:51:35

US3042192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:51:35

US3042192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 23:51:35

US3042192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 23:51:37
	(b) (4)	

US3042192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 23:51:37

US3042192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Sep 2020 21:14:54
	(b) (4)	

US3042192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered '28 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:14:54

US3042192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:14:54

US3042192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:14:54

US3042192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Sep 2020 21:14:56
	(b) (4)	

US3042192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:28:53
User entered '1'	(b) (4), (b) (6) System	14 Sep 2020 21:14:56

US3042192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:07

US3042192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:07

US3042192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:07

US3042192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:07

US3042192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:10

US3042192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:32
User entered '1'	(b) (4), (b) (6) System	14 Sep 2020 21:15:10

US3042192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:15:19

US3042192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	14 Sep 2020 21:15:19
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	14 Sep 2020 21:15:19
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'VISIT2'	(b) (4), (b) (6) System	14 Sep 2020 21:15:19

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '11 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '10:17'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered '11 Sep 2020 10:17'	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '37.1' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'bpm'	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '142'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered '84'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:01
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:16:01

US3042192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Sep 2020 21:16:52
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:16:52
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Please note that the reason for discontinuation on the dosing discontinuation form is an AE, but the Exposure form has Withdrawal of Consent. Please review and reconcile items as these need to match, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 04:44:15
Query 'Per CDM: Please note that the reason for discontinuation on the dosing discontinuation form is an AE, but the Exposure form has Withdrawal of Consent. Please review and reconcile items as these need to match, else clarify.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:55:00
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:54:50
User opened query 'Per CDM: Please note that the reason for discontinuation on the dosing discontinuation form is an AE, but the Exposure form has Withdrawal of Consent. Please review and reconcile items as these need to match, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:49:23
User closed query 'Per CDM: Please review the reason and reconcile with the Dosing discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:02:18
Query 'Per CDM: Please review the reason and reconcile with the Dosing discontinuation form. Thank you.' answered with 'REASON FOR TREATMENT NOT BEING GIVEN IS CORRECT.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:32:59
User opened query 'Per CDM: Please review the reason and reconcile with the Dosing discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:39:35
User closed query 'Per CDM re-query: If no, reason not given = Other. However, primary reason on dosing discontinuation for is recorded as Withdrawal of consent by participant. Please review reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:32:33

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

If No, reason not given

Audit	User	Time (GMT)
Query 'Per CDM re-query: If no, reason not given = Other. However, primary reason on dosing discontinuation for is recorded as Withdrawal of consent by participant. Please review reconcile and update accordingly. Thank you.' answered with 'Corrected' (Site from DM).	Jessica Knight (b) (4)	17 Nov 2020 13:45:08
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	Jessica Knight (b) (4)	17 Nov 2020 13:45:00
User opened query 'Per CDM re-query: If no, reason not given = Other. However, primary reason on dosing discontinuation for is recorded as Withdrawal of consent by participant. Please review reconcile and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:55:10
User closed query 'Per CDM: If no, reason not given = Other. Please note that this does not match the reason for discontinuation on the End of study form. Kindly, review, reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:51:42
Query 'Per CDM: If no, reason not given = Other. Please note that this does not match the reason for discontinuation on the End of study form. Kindly, review, reconcile and update as appropriate.' answered with 'ENTRY UPDATD' (Site from DM).	Rylea Gulick (b) (4)	11 Nov 2020 17:27:50
User opened query 'Per CDM: If no, reason not given = Other. Please note that this does not match the reason for discontinuation on the End of study form. Kindly, review, reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:51:25
User entered 'Other (OTHER)'	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'PARTICIPANTS LAB VALUES ARE STILL ELEVATED. DID NOT WANT TO PARTICIPATE ANY FURTHER IN THE STUDY.'	Rylea Gulick (b) (4)	11 Nov 2020 17:27:46
	(b) (4)	
reason for change: Data Entry Error		
User entered 'SUBJECTS LAB VALUES ARE STILL ELEVATED'	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:38

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:38

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:38
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:38

US3042192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:38

US3042192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:17:47

US3042192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:47
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:47
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:47

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:53
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:17:53

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:17:53

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:53
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:53

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:17:53

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Sep 2020 21:17:53
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:17:53
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:17:53

US3042192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Sep 2020 21:18:10
	(b) (4)	

US3042192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:37:35
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 21:18:10

US3042192

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:57:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:17
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:19

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:50
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 16:34:21
User entered 'ELEVATED LIVER ENZYMES'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	David Ensز (b) (4) (b) (4)	28 Apr 2021 10:00:13
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	David Ensز (b) (4) (b) (4)	28 Apr 2021 10:00:13
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '31 Aug 2020'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:13
User closed query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 13:26:57
Query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' answered with 'STOP DATE IS UNKNOWN AS SUBJECT WITHDREW CONSENT' (Site from DM).	Rylea Gulick (b) (4)	28 Jan 2021 23:46:25
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:50:17
User opened query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or confirm the AE is ongoing, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:50:12
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE WILL BE REVIEWED AND UPDATED AS NECESSARY' (Site from DM).	Rylea Gulick (b) (4)	11 Jan 2021 16:12:46
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 04:35:10
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 00:32:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 00:32:06
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Meagan Miller (b) (4)	11 Sep 2020 00:32:06
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:33:52
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:34:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 16:34:11
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	08 Sep 2020 16:34:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:33:52
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Sep 2020 00:32:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 00:32:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Meagan Miller (b) (4)	11 Sep 2020 00:32:06
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:33:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Sep 2020 00:32:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 00:32:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Meagan Miller (b) (4)	11 Sep 2020 00:32:06
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:33:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User closed query 'Per CDM: Per Dosing discontinuation form IP was withdrawn due to this AE. Kindly review, reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 06:48:24
Query 'Per CDM: Per Dosing discontinuation form IP was withdrawn due to this AE. Kindly review, reconcile and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:31:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 17:31:10
Query 'Per CDM: Per Dosing discontinuation form IP was withdrawn due to this AE. Kindly update this field accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:40:39
User opened query 'Per CDM: Per Dosing discontinuation form IP was withdrawn due to this AE. Kindly review, reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:40:34
User opened query 'Per CDM: Per Dosing discontinuation form IP was withdrawn due to this AE. Kindly update this field accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:37:13
User entered 'None (NONE)'	Rylea Gulick (b) (4) (b) (4)	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '1'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Sep 2020 16:33:52
	(b) (4)	

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '0'	(b) (4), (b) (6) System	08 Sep 2020 16:34:11

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 16:33:52

US3042192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 13:11:19

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:57:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:07:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:09:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:09:11
Data point term sent to Coder	System	15 Aug 2020 13:08:45
User entered 'LEVOTHYROXINE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'HYPOTHYROIDISM'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '100'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'ug (ug)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'once daily (QD)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed 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), (b) (6)	16 Aug 2020 17:54:39
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.'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:22
answered with 'ALL MEDICATION ONGOIN' (Site from System).	(b) (4)	
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	15 Aug 2020 13:08:09
User entered 'UN UNK 2018'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:09
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '804 (804)'	(b) (4), (b) (6) System	15 Aug 2020 13:08:09

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:10:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:10:11
Data point term sent to Coder User entered 'ALBUTEROL'	System Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:09:46 15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'ASTHMA'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose of this medication 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)	22 Sep 2020 07:28:57
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.	Rylea Gulick (b) (4)	17 Sep 2020 23:46:27
' answered with 'THIS IS THE DOSAGE PROVIDED FROM PT' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:00:21
User entered '17'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'ug (ug)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'as needed (PRN)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed 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), (b) (6)	16 Aug 2020 17:54:43
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.'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:51
answered with 'ALL MEDICATION ONGOING' (Site from System).	(b) (4)	
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	15 Aug 2020 13:08:46
User entered 'UN UNK 1985'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:08:46
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:08:46

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:10:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:10:11
Data point term sent to Coder User entered 'ZYRTEC'	System Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:09:46 15 Aug 2020 13:09:13

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:00:13
User entered 'SEASONAL ALLERGIES'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:09:13

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '10'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'mg (mg)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'once daily (QD)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User closed 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), (b) (6)	16 Aug 2020 17:54:48
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.'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:20
answered with 'ALL MEDICATION ONGOING' (Site from System).	(b) (4)	
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	15 Aug 2020 13:09:13
User entered 'UN UNK 1985'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:13
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:09:13
	(b) (4)	

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 13:09:13

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '1'	(b) (4), (b) (6) System	15 Aug 2020 13:09:13

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
User entered '804 (804)'	(b) (4), (b) (6) System	15 Aug 2020 13:09:13

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:16
Data point term sent to Coder User entered 'IBUPROFEN'	System Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:08:09 27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SOLICITED SYMPTOMS-BODY AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SOLICITED SYMPTOMS-BODY AND JOINT ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:29:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SOLICITED SYMPTOMS-BODY AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SOLICITED SYMPTOMS-BODY AND JOINT ACHES did not meet the AE reporting criteria. ' answered with 'DID NOT MEET AE REPORTING CRITERIA' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 23:46:39

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SOLICITED SYMPTOMS-BODY AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SOLICITED SYMPTOMS-BODY AND JOINT ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 04:04:38
User entered 'SOLICITED SYMPTOMS-BODY AND JOINT ACHES'	Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered '800'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'twice daily (BID)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered '15 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered '21 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:13
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered '2'	(b) (4), (b) (6) System	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered '1'	(b) (4), (b) (6) System	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered '804 (804)'	(b) (4), (b) (6) System	27 Aug 2020 18:07:35

US3042192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:57:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:11:19
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:01:37
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:30

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered '14 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 18:44:26
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:35:24
Query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' answered with 'confirmed and updated to discontinuation due to AE of elevated liver enzymes' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:27:14
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:26:50
User opened query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:26:14
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Rylea Gulick (b) (4) (b) (4)	21 Sep 2020 18:44:26

US3042192

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:30

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)	29 Apr 2021 05:09:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 08:58:12
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:02:18
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:02:12
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:14:40
User closed query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:41:03
Query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:50:47
User entered 'AE1-' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:50:42
User opened query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:35:28
User entered 'AE1- elevated liver enzymes' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:26:50
User entered 'PARTICIPANTS LAB VALUES ARE STILL ELEVATED. DID NOT WANT TO PARTICIPATE ANY FURTHER IN THE STUDY.'	Rylea Gulick (b) (4) (b) (4)	21 Sep 2020 18:44:26

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User closed query 'Per CDM , Kindly fill the dosing discontinuation page and update the appropriate fields.Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:13:50
Query 'Per CDM , Kindly fill the dosing discontinuation page and update the appropriate fields.Thanks ' answered with 'ENTRY WILL BE UPDATED' (Site from DM).	Rylea Gulick (b) (4)	21 Sep 2020 18:43:58
	(b) (4)	
User opened query 'Per CDM , Kindly fill the dosing discontinuation page and update the appropriate fields.Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:29:01
User entered '14 Sep 2020'	Rylea Gulick (b) (4)	14 Sep 2020 21:19:27
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:34:37
Query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' answered with 'updated reason for discontinuation to AE as pt withdrew consent due to AE of Elevated Liver Enzymes' (Site from DM).	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:24:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:24:26
User opened query 'Per CDM: Per End of Study form subject Withdrew consent due to elevated lab values. Please review if this relates to ELEVATED LIVER ENZYMES (AE #1) and if the primary reason for discontinuation should be updated to AE. If yes, please update as appropriate and record AE record number in the Other, specify field on this page. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:26:34
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:19:27

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

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)	29 Apr 2021 05:09:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:00:58
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 08:58:16
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:02:44
User entered 'AE #1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:02:39
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:15:03
User closed query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:41:01
Query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' answered with 'updated' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:50:21
User entered 'AE 1' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Dec 2020 22:50:15
User opened query 'Per CDM: Please note that only the AE number is to be recorded in this field and the name of is not required. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:35:21
User entered 'AE 1- elevated liver enzymes' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	23 Nov 2020 21:24:26
User entered 'PARTICIPANTS LAB VALUES ARE STILL ELEVATED. DID NOT WANT TO PARTICIPATE ANY FURTHER IN THE STUDY.'	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 21:19:27

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:19:27
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:19:27
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:19:27
	(b) (4)	

US3042192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:30

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:09:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:00:58
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Sep 2020 21:19:27
	(b) (4)	