

US3812146 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:21:21

All time stamps listed in this document are displayed in GMT

US3812146

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:21

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:21:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

Condition	BILATERAL UPPER THIGH BURNS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

Condition	BILATERAL SKIN GRAFT UPPER THIGHS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

Condition	LACERATION-ARTERIAL RIGHT FOREARM
Start date (dd MMM yyyy)	UN SEP 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2016
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

Condition	ARTERIAL REPAIR RIGHT FOREARM
Start date (dd MMM yyyy)	UN SEP 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2016
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

Condition	FORMER SMOKER
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

Condition	POST-TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

Condition	ALCOHOL ABUSE
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

Condition	METHAMPHETAMINE ABUSE
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:15 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:15
Height (<i>xxx.x</i>)	71.6 in
Weight (<i>xxx.x</i>)	230.2 lb
BMI (<i>xxx.x</i>)	31.63655 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103578

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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)	12 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:15
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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)	12 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:20
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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)	12 AUG 2020
What was the treatment time? (00:00-23:59)	14:49 (24 HR)
Treatment Date and Time (derived)	12 AUG 2020 14:49
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

12 AUG 2020

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

14:35 (24 HR)

Collection date and time (derived)

12 AUG 2020 14:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:21

Collection date (<i>dd MMM yyyy</i>)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	12 AUG 2020 14:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 15:24

PC Open Date & Time

12 AUG 2020 15:09

PC Close Date & Time

12 AUG 2020 17:39

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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 96.4 °F

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

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

PC Time Stamp	12 AUG 2020 22:16
PC Open Date & Time	12 AUG 2020 18:34
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:20

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:10

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 22:45

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 17:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:22

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

12 AUG 2020 15:25

PC Open Date & Time

12 AUG 2020 15:09

PC Close Date & Time

12 AUG 2020 17:39

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

12 AUG 2020 22:17

PC Open Date & Time

12 AUG 2020 18:34

PC Close Date & Time

13 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 16:21

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

14 AUG 2020 13:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

15 AUG 2020 22:45

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

16 AUG 2020 17:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

17 AUG 2020 16:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

18 AUG 2020 12:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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 ☐

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 15:26
PC Open Date & Time	12 AUG 2020 15:09
PC Close Date & Time	12 AUG 2020 17:39

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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 ☐

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 22:17
PC Open Date & Time	12 AUG 2020 18:34
PC Close Date & Time	13 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	13 AUG 2020 16:22
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	14 AUG 2020 13:12
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	15 AUG 2020 22:46
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	16 AUG 2020 17:44
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	17 AUG 2020 16:36
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

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 ☒

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

Yes ☐	
PC Time stamp	18 AUG 2020 12:23
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3812146

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812146

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812146

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

Was Contact Attempted?

Yes ☒

No ☐

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

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812146

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812146

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

Was Contact Attempted?

Yes ☒

No ☐

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

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812146

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812146

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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	VISIT2

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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	

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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	

US3812146

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

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.

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☒
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3812146

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:21

Collection date (*dd MMM yyyy*)

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

US3812146

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

Date of Contact	12 AUG 2020
Time of Contact	12:55
Date and Time of Contact (derived)	12 AUG 2020 12:55
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 ☒

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:21:21

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812146

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:21

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3812146

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:21

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

Yes ☐

No ☒

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

US3812146

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3812146

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:21

Date of dosing discontinuation (dd MMM yyyy)

12 AUG 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 _____

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

Date of study discontinuation/completion (dd MMM yyyy) 02 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

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

US3812146 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812146

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812146'	RWS_ENDPOINT ENDPOINT (b) (4) 	12 Aug 2020 19:19:29

US3812146

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:38

US3812146

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 19:19:30

US3812146

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:38

US3812146

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Aug 2020 20:01:38

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 19:19:31

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Age](#)

Audit	User	Time (GMT)
User entered '41'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '41'	System	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

White

Audit	User	Time (GMT)
User entered '1'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	12 Aug 2020 20:05:20

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:47

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 19:19:30

US3812146

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:09:10

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Thermal burns, PT: Thermal burn, LLT: Burn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:32:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:32:35
Data point term sent to Coder	System	19 Aug 2020 22:11:08
User entered 'BILATERAL UPPER THIGH BURNS'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2008'	System	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2008'	System	19 Aug 2020 22:10:41

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 00:03:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 00:03:18
Data point term sent to Coder	System	19 Aug 2020 22:11:09
User entered 'BILATERAL SKIN GRAFT UPPER THIGHS'	Breanna Galibert (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2008'	System	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2008'	System	19 Aug 2020 22:11:01

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cardiovascular injuries, PT: Arterial injury, LLT: Arterial laceration - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 13:14:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 13:14:43
Data point term sent to Coder	System	19 Aug 2020 22:13:11
User entered 'LACERATION-ARTERIAL RIGHT FOREARM'	Breanna Galibert (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN Sep 2016'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN Sep 2016'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Sep 2016'	System	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2016'	System	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Sep 2016'	System	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2016'	System	19 Aug 2020 22:12:25

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Arterial repair, LLT: Arterial repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:17:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:17:07
Data point term sent to Coder	System	19 Aug 2020 22:13:11
User entered 'ARTERIAL REPAIR RIGHT FOREARM'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN Sep 2016'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:32:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:32:51
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	04 Sep 2020 16:32:51
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 22:12:47
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'un Sep 2016' reason for change: Data Entry Error	Anya Penly (b) (4)	04 Sep 2020 16:32:51
User entered empty.	Breanna Galibert (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Sep 2016'	System	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2016'	System	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Sep 2016'	System	04 Sep 2020 16:32:51
User entered empty.	System	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2016'	System	04 Sep 2020 16:32:51
User entered empty.	System	19 Aug 2020 22:12:47

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:14:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:14:16
Data point term sent to Coder	System	19 Aug 2020 22:13:11
User entered 'TONSILLITIS'	Breanna Galibert (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1991'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1991'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1991'	System	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1991'	System	19 Aug 2020 22:13:02

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:15:19
Data point term sent to Coder	System	19 Aug 2020 22:14:12
User entered 'TONSILLECTOMY'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1991'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1991'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1991'	System	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1991'	System	19 Aug 2020 22:13:23

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-smoker - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:15:19
Data point term sent to Coder	System	19 Aug 2020 22:14:12
User entered 'FORMER SMOKER'	Breanna Galibert (b) (4)	19 Aug 2020 22:13:38
	(b) (4)	

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1994'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1994'	System	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2018'	System	19 Aug 2020 22:13:38

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:15:19
Data point term sent to Coder	System	19 Aug 2020 22:14:12
User entered 'PENICILLIN ALLERGY'	Breanna Galibert (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1984'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1984'	System	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:13:54

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:16:27
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:35:46
Data point term sent to Coder	System	22 Sep 2020 15:34:40
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:34:31
Coding entries removed.	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:34:23
User entered 'Post-traumatic stress disorder' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:34:23
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:35:52
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:15:19
Data point term sent to Coder	System	19 Aug 2020 22:14:12
User entered 'PTSD'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1995'	System	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:14:03

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:16:30
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:36:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:36:38
Data point term sent to Coder	System	22 Sep 2020 15:35:43
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:35:01
Coding entries removed.	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:34:52
User entered 'Attention deficit disorder' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	22 Sep 2020 15:34:52
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 22:42:24
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:16:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:16:05
Data point term sent to Coder	System	19 Aug 2020 22:15:15
User entered 'ADD'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1995'	System	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:14:13

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:16:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 22:16:05
Data point term sent to Coder	System	19 Aug 2020 22:15:15
User entered 'ALCOHOL ABUSE'	Breanna Galibert (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1994'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1994'	System	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2018'	System	19 Aug 2020 22:14:30

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Amphetamine abuse - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:17:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 23:17:57
Data point term sent to Coder	System	19 Aug 2020 22:15:13
User entered 'METHAMPHETAMINE ABUSE'	Breanna Galibert (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1997'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1997'	System	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2018'	System	19 Aug 2020 22:14:52

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '13:15'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:15'	System	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '71.6' in	Breanna Galibert (b) (4)	19 Aug 2020 22:15:32
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '230.2' lb	Breanna Galibert (b) (4)	19 Aug 2020 22:15:32
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '31.63655'	System	16 Sep 2020 23:54:11
User entered '31.6'	System	19 Aug 2020 22:15:32
DataPoint set to visible.	System	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	19 Aug 2020 22:15:32
DataPoint set to visible.	System	12 Aug 2020 20:01:51

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:15:32

US3812146

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:40

US3812146

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:15:40

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:05

US3812146

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:00

US3812146

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:00

US3812146

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:00

US3812146

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	12 Aug 2020 20:02:00

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	12 Aug 2020 19:19:34

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:58:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:58:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 19:19:34
User entered '103578' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 19:19:34

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 19:19:34

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:30

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:30

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:30

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:30

US3812146

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:30

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '13:15'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:15'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '16'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:58:55
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 22:18:05
User entered '15:20'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:20'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Pulse (xxx)

Audit	User	Time (GMT)
User entered '52'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '16'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 22:18:05

US3812146

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:37

US3812146

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:37

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:02:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 20:02:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 20:02:36
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 20:02:42
User entered empty.	System	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '14:49'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 14:49'	System	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Aug 2020 20:02:42
User entered empty.	System	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 20:02:42
User entered empty.	System	12 Aug 2020 20:02:36

US3812146

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:49

US3812146

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:49

US3812146

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:35'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:16:49

US3812146

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 14:35'	System	19 Aug 2020 22:16:49

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:38'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 14:38'	System	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:17:00

US3812146

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:19:01

US3812146

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 22:19:01

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:23:48', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '70afbb4f-20eb-4323-b692-a525eac3562c'	System	12 Aug 2020 20:24:38
User entered 'Yes (Y)'	System	12 Aug 2020 20:24:38

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:23:57', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '70afbb4f-20eb-4323-b692-a525eac3562c'	System	12 Aug 2020 20:24:38
User entered '97.5'	System	12 Aug 2020 20:24:38

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:24:05', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '70afbb4f-20eb-4323-b692-a525eac3562c'	System	12 Aug 2020 20:24:38
User entered 'No (N)'	System	12 Aug 2020 20:24:38

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:24:36', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '70afbb4f-20eb-4323-b692-a525eac3562c'	System	12 Aug 2020 20:24:38
User entered '12 Aug 2020 15:24'	System	12 Aug 2020 20:24:38

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:09'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:39'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:16:28', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '378988ac-d8d2-42ad-98c5-92ef98f8f0f1'	System	13 Aug 2020 03:18:47
User entered 'Yes (Y)'	System	13 Aug 2020 03:18:47

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:16:36', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '378988ac-d8d2-42ad-98c5-92ef98f8f0f1'	System	13 Aug 2020 03:18:47
User entered '96.4'	System	13 Aug 2020 03:18:47

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:16:44', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '378988ac-d8d2-42ad-98c5-92ef98f8f0f1'	System	13 Aug 2020 03:18:47
User entered 'No (N)'	System	13 Aug 2020 03:18:47

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:16:48', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '378988ac-d8d2-42ad-98c5-92ef98f8f0f1'	System	13 Aug 2020 03:18:47
User entered '12 Aug 2020 22:16'	System	13 Aug 2020 03:18:47

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:34'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 2'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:20:34', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4773d77-9fd9-4873-b9e1-100da6531fe5'	System	13 Aug 2020 21:20:59
User entered 'Yes (Y)'	System	13 Aug 2020 21:20:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:20:45', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4773d77-9fd9-4873-b9e1-100da6531fe5'	System	13 Aug 2020 21:20:59
User entered '97.4'	System	13 Aug 2020 21:20:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:20:52', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4773d77-9fd9-4873-b9e1-100da6531fe5'	System	13 Aug 2020 21:20:59
User entered 'No (N)'	System	13 Aug 2020 21:20:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:20:55', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4773d77-9fd9-4873-b9e1-100da6531fe5'	System	13 Aug 2020 21:20:59
User entered '13 Aug 2020 16:20'	System	13 Aug 2020 21:20:59

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 3'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:10:19', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '94b49413-1b1a-4583-91eb-b43188e6f6a8'	System	17 Aug 2020 16:57:09
User entered 'Yes (Y)'	System	17 Aug 2020 16:57:09

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:10:27', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '94b49413-1b1a-4583-91eb-b43188e6f6a8'	System	17 Aug 2020 16:57:09
User entered '96.4'	System	17 Aug 2020 16:57:09

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:10:47', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '94b49413-1b1a-4583-91eb-b43188e6f6a8'	System	17 Aug 2020 16:57:09
User entered 'No (N)'	System	17 Aug 2020 16:57:09

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:10:50', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '94b49413-1b1a-4583-91eb-b43188e6f6a8'	System	17 Aug 2020 16:57:09
User entered '14 Aug 2020 13:10'	System	17 Aug 2020 16:57:09

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 4'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:08', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '97df8a6b-dc96-4e31-89cf-7ebd4f7d3c19'	System	17 Aug 2020 16:57:10
User entered 'Yes (Y)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:15', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '97df8a6b-dc96-4e31-89cf-7ebd4f7d3c19'	System	17 Aug 2020 16:57:10
User entered '96.4'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:22', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '97df8a6b-dc96-4e31-89cf-7ebd4f7d3c19'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:25', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '97df8a6b-dc96-4e31-89cf-7ebd4f7d3c19'	System	17 Aug 2020 16:57:10
User entered '15 Aug 2020 22:45'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 5'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:42:53', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '16a0dd5a-3bdf-42e9-aa67-3dfef57daa15'	System	17 Aug 2020 16:57:11
User entered 'Yes (Y)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:03', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '16a0dd5a-3bdf-42e9-aa67-3dfef57daa15'	System	17 Aug 2020 16:57:11
User entered '97.3'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:08', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '16a0dd5a-3bdf-42e9-aa67-3dfef57daa15'	System	17 Aug 2020 16:57:11
User entered 'No (N)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:10', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '16a0dd5a-3bdf-42e9-aa67-3dfef57daa15'	System	17 Aug 2020 16:57:11
User entered '16 Aug 2020 17:43'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 6'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:34:51', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'f1454540-13d8-45cd-95c3-b42bd982a20d'	System	17 Aug 2020 21:35:13
User entered 'Yes (Y)'	System	17 Aug 2020 21:35:13

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'f1454540-13d8-45cd-95c3-b42bd982a20d'	System	17 Aug 2020 21:35:13
User entered '97.3'	System	17 Aug 2020 21:35:13

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:05', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'f1454540-13d8-45cd-95c3-b42bd982a20d'	System	17 Aug 2020 21:35:13
User entered 'No (N)'	System	17 Aug 2020 21:35:13

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:10', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'f1454540-13d8-45cd-95c3-b42bd982a20d'	System	17 Aug 2020 21:35:13
User entered '17 Aug 2020 16:35'	System	17 Aug 2020 21:35:13

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 7'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:29', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'dcb7a42c-c2a3-4eeb-9af0-f8eda4af7429'	System	18 Aug 2020 17:22:45
User entered 'Yes (Y)'	System	18 Aug 2020 17:22:45

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:35', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'dcb7a42c-c2a3-4eeb-9af0-f8eda4af7429'	System	18 Aug 2020 17:22:45
User entered '96.4'	System	18 Aug 2020 17:22:45

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:39', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'dcb7a42c-c2a3-4eeb-9af0-f8eda4af7429'	System	18 Aug 2020 17:22:45
User entered 'No (N)'	System	18 Aug 2020 17:22:45

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:42', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'dcb7a42c-c2a3-4eeb-9af0-f8eda4af7429'	System	18 Aug 2020 17:22:45
User entered '18 Aug 2020 12:22'	System	18 Aug 2020 17:22:45

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:24:54', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '9dcce8d0-e537-41e4-b477-fc3ce7f591d8'	System	12 Aug 2020 20:25:33
User entered 'None (1)'	System	12 Aug 2020 20:25:33

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:24:59', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '9dcce8d0-e537-41e4-b477-fc3ce7f591d8'	System	12 Aug 2020 20:25:33
User entered 'No (N)'	System	12 Aug 2020 20:25:33

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:13', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '9dcce8d0-e537-41e4-b477-fc3ce7f591d8'	System	12 Aug 2020 20:25:33
User entered 'No (N)'	System	12 Aug 2020 20:25:33

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:23', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '9dcce8d0-e537-41e4-b477-fc3ce7f591d8'	System	12 Aug 2020 20:25:33
User entered 'None (1)'	System	12 Aug 2020 20:25:33

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:30', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '9dcce8d0-e537-41e4-b477-fc3ce7f591d8'	System	12 Aug 2020 20:25:33
User entered '12 Aug 2020 15:25'	System	12 Aug 2020 20:25:33

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:09'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:39'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4774d93-0240-41fe-afaa-1690f93c7ae7'	System	13 Aug 2020 03:18:48
User entered 'None (1)'	System	13 Aug 2020 03:18:48

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:06', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4774d93-0240-41fe-afaa-1690f93c7ae7'	System	13 Aug 2020 03:18:48
User entered 'No (N)'	System	13 Aug 2020 03:18:48

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:12', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4774d93-0240-41fe-afaa-1690f93c7ae7'	System	13 Aug 2020 03:18:48
User entered 'No (N)'	System	13 Aug 2020 03:18:48

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:18', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4774d93-0240-41fe-afaa-1690f93c7ae7'	System	13 Aug 2020 03:18:48
User entered 'None (1)'	System	13 Aug 2020 03:18:48

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:21', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'a4774d93-0240-41fe-afaa-1690f93c7ae7'	System	13 Aug 2020 03:18:48
User entered '12 Aug 2020 22:17'	System	13 Aug 2020 03:18:48

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:34'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 2'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:03', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '35af9502-79a4-4650-82a3-7512fcae44a3'	System	13 Aug 2020 21:21:24
User entered 'None (1)'	System	13 Aug 2020 21:21:24

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:07', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '35af9502-79a4-4650-82a3-7512fcae44a3'	System	13 Aug 2020 21:21:24
User entered 'No (N)'	System	13 Aug 2020 21:21:24

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:12', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '35af9502-79a4-4650-82a3-7512fcae44a3'	System	13 Aug 2020 21:21:24
User entered 'No (N)'	System	13 Aug 2020 21:21:24

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:18', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '35af9502-79a4-4650-82a3-7512fcae44a3'	System	13 Aug 2020 21:21:24
User entered 'None (1)'	System	13 Aug 2020 21:21:24

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:23', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '35af9502-79a4-4650-82a3-7512fcae44a3'	System	13 Aug 2020 21:21:24
User entered '13 Aug 2020 16:21'	System	13 Aug 2020 21:21:24

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 3'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '0ec5968d-4126-43ad-982d-91fb6369541e'	System	17 Aug 2020 16:57:10
User entered 'None (1)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:04', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '0ec5968d-4126-43ad-982d-91fb6369541e'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:06', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '0ec5968d-4126-43ad-982d-91fb6369541e'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:09', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '0ec5968d-4126-43ad-982d-91fb6369541e'	System	17 Aug 2020 16:57:10
User entered 'None (1)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:11', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '0ec5968d-4126-43ad-982d-91fb6369541e'	System	17 Aug 2020 16:57:10
User entered '14 Aug 2020 13:11'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 4'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:32', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '8411db30-4195-4d48-a727-0b76be51fa9c'	System	17 Aug 2020 16:57:10
User entered 'None (1)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:41', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '8411db30-4195-4d48-a727-0b76be51fa9c'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:44', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '8411db30-4195-4d48-a727-0b76be51fa9c'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:49', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '8411db30-4195-4d48-a727-0b76be51fa9c'	System	17 Aug 2020 16:57:10
User entered 'None (1)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:52', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '8411db30-4195-4d48-a727-0b76be51fa9c'	System	17 Aug 2020 16:57:10
User entered '15 Aug 2020 22:45'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 5'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:20', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '2a69a1f4-a440-429c-a883-bcb6b6776437'	System	17 Aug 2020 16:57:11
User entered 'None (1)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:26', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '2a69a1f4-a440-429c-a883-bcb6b6776437'	System	17 Aug 2020 16:57:11
User entered 'No (N)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:30', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '2a69a1f4-a440-429c-a883-bcb6b6776437'	System	17 Aug 2020 16:57:11
User entered 'No (N)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:32', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '2a69a1f4-a440-429c-a883-bcb6b6776437'	System	17 Aug 2020 16:57:11
User entered 'None (1)'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:35', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '2a69a1f4-a440-429c-a883-bcb6b6776437'	System	17 Aug 2020 16:57:11
User entered '16 Aug 2020 17:43'	System	17 Aug 2020 16:57:11

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 6'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:15', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'ccef1696-bcbc-48c4-90bb-35df3954d638'	System	17 Aug 2020 21:35:34
User entered 'None (1)'	System	17 Aug 2020 21:35:34

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:20', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'ccef1696-bcbc-48c4-90bb-35df3954d638'	System	17 Aug 2020 21:35:34
User entered 'No (N)'	System	17 Aug 2020 21:35:34

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:23', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'ccef1696-bcbc-48c4-90bb-35df3954d638'	System	17 Aug 2020 21:35:34
User entered 'No (N)'	System	17 Aug 2020 21:35:34

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:28', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'ccef1696-bcbc-48c4-90bb-35df3954d638'	System	17 Aug 2020 21:35:34
User entered 'None (1)'	System	17 Aug 2020 21:35:34

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:30', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'ccef1696-bcbc-48c4-90bb-35df3954d638'	System	17 Aug 2020 21:35:34
User entered '17 Aug 2020 16:35'	System	17 Aug 2020 21:35:34

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 7'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:47', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '5f6f0a84-55e8-4ac8-a010-b8d7d1ae9daf'	System	18 Aug 2020 17:23:02
User entered 'None (1)'	System	18 Aug 2020 17:23:02

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:50', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '5f6f0a84-55e8-4ac8-a010-b8d7d1ae9daf'	System	18 Aug 2020 17:23:02
User entered 'No (N)'	System	18 Aug 2020 17:23:02

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:54', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '5f6f0a84-55e8-4ac8-a010-b8d7d1ae9daf'	System	18 Aug 2020 17:23:02
User entered 'No (N)'	System	18 Aug 2020 17:23:02

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:22:57', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '5f6f0a84-55e8-4ac8-a010-b8d7d1ae9daf'	System	18 Aug 2020 17:23:02
User entered 'None (1)'	System	18 Aug 2020 17:23:02

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '5f6f0a84-55e8-4ac8-a010-b8d7d1ae9daf'	System	18 Aug 2020 17:23:02
User entered '18 Aug 2020 12:23'	System	18 Aug 2020 17:23:02

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:37', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:39', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:42', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:47', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:49', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:25:51', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'None (0)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:26:05', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered 'No (N)'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T15:26:09', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '85b1e9e5-9e7d-480f-9d42-595a41740c9d'	System	12 Aug 2020 20:26:11
User entered '12 Aug 2020 15:26'	System	12 Aug 2020 20:26:11

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:09'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 17:39'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:26', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:29', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:35', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:40', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:43', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:46', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'None (0)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:56', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered 'No (N)'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-12T22:17:59', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'b04d813d-fc53-4926-90c4-d27646d31954'	System	13 Aug 2020 03:18:49
User entered '12 Aug 2020 22:17'	System	13 Aug 2020 03:18:49

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:34'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 2'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:28', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:31', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:37', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:43', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:46', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:21:53', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'None (0)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:22:03', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered 'No (N)'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-13T16:22:06', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '57c409d5-5429-4668-89a6-3d40e2dae252'	System	13 Aug 2020 21:22:09
User entered '13 Aug 2020 16:22'	System	13 Aug 2020 21:22:09

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 3'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:16', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:19', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:21', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:23', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:26', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:11:40', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'None (0)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:12:27', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered 'No (N)'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-14T13:12:30', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '79fcd15b-331b-4972-b993-fda7ea65b709'	System	17 Aug 2020 16:57:10
User entered '14 Aug 2020 13:12'	System	17 Aug 2020 16:57:10

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 4'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:45:58', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:01', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:03', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:07', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:10', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:12', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:19', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered 'No (N)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-15T22:46:22', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '794734a7-27b1-4c16-b4ac-3fbef94c7bb0'	System	17 Aug 2020 16:57:12
User entered '15 Aug 2020 22:46'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 5'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:40', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:42', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:44', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:47', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:52', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:54', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'None (0)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:43:58', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered 'No (N)'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-16T17:44:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: 'e3425c09-7687-448b-814d-6e5b415a69b0'	System	17 Aug 2020 16:57:12
User entered '16 Aug 2020 17:44'	System	17 Aug 2020 16:57:12

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 6'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:35', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:39', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:41', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:45', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:47', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:35:50', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'None (0)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:36:00', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered 'No (N)'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-17T16:36:02', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '453f898d-55e4-47b3-b7cf-10ac70aee937'	System	17 Aug 2020 21:36:04
User entered '17 Aug 2020 16:36'	System	17 Aug 2020 21:36:04

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:02:36
User entered 'Day 7'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:05', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:07', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:09', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:12', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:15', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:17', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'None (0)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:23', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered 'No (N)'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3488C956-DDE5-4028-B236-D90265943D2E)', Time: '2020-08-18T12:23:25', User OID: 'PatientReportedOutcome (US3812146)', ODM File OID: '18028176-931e-4e9c-a85a-05987426ca42'	System	18 Aug 2020 17:23:27
User entered '18 Aug 2020 12:23'	System	18 Aug 2020 17:23:27

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:02:36

US3812146

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:02:36

US3812146

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:19:26

US3812146

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:19:26

US3812146

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:19:26

US3812146

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:19:26

US3812146

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	29 Aug 2020 17:45:35

US3812146

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:45:35

US3812146

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	29 Aug 2020 17:45:54

US3812146

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Angie Kean (b) (4) (b) (4)	29 Aug 2020 17:45:54

US3812146

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	29 Aug 2020 17:45:54

US3812146

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	29 Aug 2020 17:45:54

US3812146

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 15:12:52

US3812146

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:12:52

US3812146

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:57:01

US3812146

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:57:01

US3812146

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:57:01

US3812146

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	03 Sep 2020 19:57:01

US3812146

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	13 Sep 2020 10:51:14

US3812146

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 10:51:14

US3812146

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:54:44

US3812146

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:54:44

US3812146

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:54:44

US3812146

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	31 Oct 2020 17:54:44

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:56:09

US3812146

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:20

US3812146

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:20

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		31 Oct 2020 19:12:06
User entered 'Lost To Follow-Up (LOST TO FOLLOW-UP)' reason for change: Data Entry Error	Karen Knapp (b) (4)	31 Oct 2020 19:12:06
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	31 Oct 2020 17:55:26
	Heather Cherniawski	31 Oct 2020 17:55:26
	(b) (4)	

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:26

US3812146

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:33

US3812146

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:33

US3812146

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:33

US3812146

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:33

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:59

US3812146

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	31 Oct 2020 17:55:02

US3812146

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 17:55:02

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Lyly Dang (b) (4)	04 Sep 2020 23:04:20

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '12:55'	Lyly Dang (b) (4)	04 Sep 2020 23:04:20

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:55'	System	04 Sep 2020 23:04:20

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Lyly Dang (b) (4) Scheduled)'	[REDACTED] [REDACTED]	04 Sep 2020 23:04:20

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 23:04:20

US3812146

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:21:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 12:51:36

US3812146

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Sep 2020 19:54:06
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Aug 2020 17:07:33

US3812146

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Aug 2020 22:18:18

US3812146

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 15:12:19

US3812146

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:21

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:35:28
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' answered with 'Updated for last IP dose received. Thank you' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 17:35:47
User entered '12 Aug 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 17:35:33
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:32:52
User entered '15 Aug 2020'	Lyly Dang (b) (4)	18 Oct 2020 01:22:39

US3812146

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:41:53
Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you.' answered with 'Subject was Postive for SARS-COV-2 at baseline and was asymptomatic. Therefore, no AE was written or COVID-19 Assessment was performed. Thank you' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 17:37:00
User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:33:21
User entered 'Due to SARS-COV-2 (COVID)'	Lyly Dang (b) (4)	18 Oct 2020 01:22:39

US3812146

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:22:39

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if date of last contact is "16 Oct 2020" or Safety Call Day 22 (02 Sept 2020). Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:52:53
Query 'Per CDM: Please confirm if date of last contact is "16 Oct 2020" or Safety Call Day 22 (02 Sept 2020). Please review and reconcile. Thank you.'	Lyly Dang (b) (4)	26 Oct 2020 17:34:52
answered with 'Last contact is 02 sep 2020. EDC updated. Thank you' (Site from DM).		
User entered '02 Sep 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 17:34:36
User opened query 'Per CDM: Please confirm if date of last contact is "16 Oct 2020" or Safety Call Day 22 (02 Sept 2020). Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:51:10
User entered '16 Oct 2020'	Lyly Dang (b) (4)	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:23:53

US3812146

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:21

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	18 Oct 2020 01:23:53