US3322341 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Participant ID US3322341

mRNA-1273-P301 Completion Guidelines

US3322341

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	12 SEP 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

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
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

US3322341

Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Date of Informed Consent *(dd MMM yyyy)*	12 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3322341

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Did the participant meet all eligibility criteria?　　　　　　　　　Yes ⬤

No ◯

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

Were any significant conditions reported?   Yes ⬤

                                                          No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	BROKEN LEFT ANKLE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	BROKEN LEFT WRIST
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

Condition	L1 FRACTURE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	IRREGULAR MENSTRUATION
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	PENICILLIN ALLERGY (HIVES)
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (10)

Data signed: ▒ (b) (4) ▒ **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	RIGHT ELBOW CUBITAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

Folder: Screening

Form: Medical History (11)

Data signed: ▨ (b) (4) ▨ **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	CUBITAL TUNNEL RELEASE SURGERY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (12)

Data signed: [b) (4)] **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	RIGHT KNEE ARTHROSCOPIC LATERAL RELEASE SURGERY
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (13)

Data signed: [(b) (4)] **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	RIGHT KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	BUNION ON RIGHT TOE
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	RIGHT TOE BUNION EXCISION
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	CROSS BITE
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

Condition	JAW REALIGNMENT SURGERY
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	EXACERBATION OF SEASONAL ALLERGIES
Start date (dd MMM yyyy)	28 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ⚪
	No ⚫
If No, please specify the stop date (dd MMM yyyy)	30 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	UTERINE FIBROID (SUBMUCOSAL LEIOMYOMA)
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	28 DEC 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	DEC 2020
Stop Year (derived)	2020

US3322341

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) **03 May 2021 23:13:32**

Generated On: 09 Jun 2021 17:05:24

Condition	FACE TIGHTENING COSMETIC PROCEDURE, ELECTIVE
Start date (dd MMM yyyy)	31 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	31 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3322341

Folder: Screening

Form: Vital Signs

Data signed: [(b) (4)] 26 Feb 2021 04:03:00

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 SEP 2020
Time of assessment *(00:00-23:59)*	14:30 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 14:30
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	128.4 lb
BMI *(xxx.x)*	22.79260 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322341

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   12 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*	12 SEP 2020
Is the participant of childbearing potential?	Yes ●
	No ○
If No, what is the reason?	Surgically sterile ○
	Post-menopausal ○
	Partner medically sterile ○
	Not reached age of Menarche ○
	Other ○
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

US3322341

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	12 SEP 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

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		DRIVER FOR A MEAL PREP KITCHEN; WILL SEE 6 PEOPLE AT WORK (EVERYONE WEARS FACE MASKS & SOCIAL DISTANCE)

Location and Living Circumstances Risk (check all that apply)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

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
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	1-2X A WEEK EAT OUT; 7 DAYS A WEEK GOES TO GYM; GROCERY SHOPPING 7X A WEEK; SEES FRIENDS 1-2X A WEEK USUALLY LESS THAN 10 PEOPLE AT A TIME GOES TO COFFEE SHOP 3X WEEK

US3322341
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 04:03:01**
Generated On: 09 Jun 2021 17:05:24

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: [(b) (4)] **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

What was the date of randomization? *(dd MMM yyyy)*	01 OCT 2020
What was the participant's randomization number?	116264

In what Cohort was the participant enrolled?

>=18 and <65 years and not at risk ●

>=18 and <65 years and at risk ○

>=65 years ○

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

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

Yes ○
No ●

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

Yes ○
No ●

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

Yes ○
No ●

Diabetes (Type I, Type 2, or gestational)

Yes ○
No ●

Liver Disease

Yes ○
No ●

Human Immunodeficiency Virus (HIV) infection

Yes ○
No ●

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **26 Feb 2021 04:03:01**
Generated On: 09 Jun 2021 17:05:24

Height	63 in
Weight	125.7 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Height	63 in
Weight	125.7 lb
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	1 OCT 2020
Time of assessment *(00:00-23:59)*	15:30 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 15:30
Temperature *(xxx.x)*	99.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Height	63 in
Weight	125.7 lb
Timepoint	Pre-Dose ⬭
	Post-Dose ⬛
Were vital signs assessed?	Yes ⬛
	No ⬭
Date of assessment *(dd MMM yyyy)*	1 OCT 2020
Time of assessment *(00:00-23:59)*	17:37 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 17:37
Temperature *(xxx.x)*	99.0 F
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?   Yes ●

                                                                        No ◯

Date of examination *(dd MMM yyyy)*   1 OCT 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: Visit 1 Day 1

Form: Pregnancy Test

Data signed: ▨ (b) (4) ▨ **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	1 OCT 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

Was study treatment given?	Yes ●
	No ◯

If No, reason not given	
	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	01 OCT 2020
What was the treatment time? *(00:00-23:59)*	17:02 (24 HR)
Treatment Date and Time (derived)	01 OCT 2020 17:02
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	1 OCT 2020
Collection time *(00:00-23:59)*	16:24 (24 HR)
Collection date and time (derived)	1 OCT 2020 16:24

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Feb 2021 04:03:00**

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*			1 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:20	1 OCT 2020 16:20
Nasopharyngeal Swab 2	No		

US3322341
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 04:03:00**
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 OCT 2020 17:39
PC Open Date & Time	01 OCT 2020 17:22
PC Close Date & Time	01 OCT 2020 19:52

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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**	101.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	01 OCT 2020 21:58
PC Open Date & Time	01 OCT 2020 20:47
PC Close Date & Time	02 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24

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**	99.3 °F

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

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

PC Time Stamp	02 OCT 2020 21:27
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °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	03 OCT 2020 22:07
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0784179

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.5 °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	04 OCT 2020 22:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	05 OCT 2020 13:40
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24

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.

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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	06 OCT 2020 15:07
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	07 OCT 2020 19:09
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	01 OCT 2020 17:40
PC Open Date & Time	01 OCT 2020 17:22
PC Close Date & Time	01 OCT 2020 19:52

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	01 OCT 2020 21:59
PC Open Date & Time	01 OCT 2020 20:47
PC Close Date & Time	02 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	02 OCT 2020 21:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	03 OCT 2020 22:08
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	04 OCT 2020 22:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	05 OCT 2020 13:40
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	06 OCT 2020 15:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	07 OCT 2020 19:09
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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 ◯

Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No	⬤
	Yes	◯

PC Time stamp	01 OCT 2020 17:41
PC Open Date & Time	01 OCT 2020 17:22
PC Close Date & Time	01 OCT 2020 19:52

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE
- None ○
- No interference with activity ●
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	01 OCT 2020 22:00
PC Open Date & Time	01 OCT 2020 20:47
PC Close Date & Time	02 OCT 2020 11:59

Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 2

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	02 OCT 2020 21:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

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 ⬤

	Yes ◯
PC Time stamp	03 OCT 2020 22:09
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

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 ●

FDA-CBER-2022-1614-0784200

	Yes ◯
PC Time stamp	04 OCT 2020 22:27
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 5

HEADACHE

- ● None
- ○ No interference with activity
- ○ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- ○ Any use of prescription pain reliever or prevents daily activity

FATIGUE

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- ● None
- ○ No interference with activity
- ○ Some interference with activity
- ○ Significant; prevents daily activity

NAUSEA/VOMITING

- ● None
- ○ No interference with activity or 1-2 episodes/24 hours
- ○ Some interference with activity or >2 episodes/24 hours
- ○ Prevents daily activity, requires outpatient IV hydration

CHILLS

- ● None
- ○ No interference with activity
- ○ Some interference with activity not requiring medical attention
- ○ Prevents daily activity and requires medical attention

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — ● No

PRODUCTION RELEASE (v12.003 EAB) (1725)

	Yes ⬤
PC Time stamp	05 OCT 2020 13:41
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

TIMEPOINT	DAY 6

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	06 OCT 2020 15:09
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24

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 ●

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24

	Yes ◯
PC Time stamp	07 OCT 2020 19:10
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3322341

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3322341

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag 1

US3322341

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 15 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ◯

Continuing Flag   1

US3322341
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 04:02:59**
Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                              No ◯

Continuing Flag   1

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 29 OCT 2020 |

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

| Folder OID | VISIT2 |

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	29 OCT 2020
Time of assessment *(00:00-23:59)*	14:45 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 14:45
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	29 OCT 2020
Time of assessment *(00:00-23:59)*	16:40 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 16:40
Temperature *(xxx.x)*	99.0 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3322341

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?   Yes ●

                                                            No ○

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

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

Was the pregnancy test performed?	Yes ●
	No ○
Date of test *(dd MMM yyyy)*	29 OCT 2020
Test performed	Urine ●
	Serum ○
Result	Positive ○
	Negative ●
Was FSH sample collected?	Yes ○
	No ●
Collection date	
Collection time	
Collection date and time (derived)	

Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **26 Feb 2021 04:03:30**
Generated On: 09 Jun 2021 17:05:24

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)*	29 OCT 2020
What was the treatment time? *(00:00-23:59)*	16:06 (24 HR)
Treatment Date and Time (derived)	29 OCT 2020 16:06
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

US3322341

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	29 OCT 2020
Collection time *(00:00-23:59)*	15:35 (24 HR)
Collection date and time (derived)	29 OCT 2020 15:35

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Feb 2021 04:03:01**

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*   29 OCT 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:27	29 OCT 2020 15:27
Nasopharyngeal Swab 2	No		

US3322341

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:03:30

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?	Yes	●
	No	○

Continuing Flag	1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 OCT 2020 16:41
PC Open Date & Time	29 OCT 2020 16:26
PC Close Date & Time	29 OCT 2020 18:56

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**	99.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	29 OCT 2020 21:01
PC Open Date & Time	29 OCT 2020 19:51
PC Close Date & Time	30 OCT 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.7 °F

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

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

PC Time Stamp	30 OCT 2020 12:02
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	31 OCT 2020 22:14
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ●
	No ○
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ○
	No ●

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

PC Time Stamp	01 NOV 2020 19:26
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

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.

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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.

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	02 NOV 2020 23:37
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.1 °F

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

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

PC Time Stamp	03 NOV 2020 13:59
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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	29 OCT 2020 16:41
PC Open Date & Time	29 OCT 2020 16:26
PC Close Date & Time	29 OCT 2020 18:56

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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	29 OCT 2020 21:01
PC Open Date & Time	29 OCT 2020 19:51
PC Close Date & Time	30 OCT 2020 11:59

TIMEPOINT	DAY 2

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	30 OCT 2020 12:03
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

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

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

Yes	⬤
No	◯

Please record - **REDNESS AT INJECTION SITE (in mm)** — 9

Measure the largest size across any injection site redness with the ruler provided.

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

Yes	⬤
No	◯

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** — 9

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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	31 OCT 2020 22:18
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

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

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

- Yes ○
- No ●

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

- Yes ○
- No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

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

PC Time Stamp	01 NOV 2020 19:27
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	02 NOV 2020 23:37
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	03 NOV 2020 13:59
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 7

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	04 NOV 2020 15:06
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24

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 ○

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	29 OCT 2020 16:42
PC Open Date & Time	29 OCT 2020 16:26
PC Close Date & Time	29 OCT 2020 18:56

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	29 OCT 2020 21:02
PC Open Date & Time	29 OCT 2020 19:51
PC Close Date & Time	30 OCT 2020 11:59

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 2

HEADACHE
- None ○
- No interference with activity ●
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

PRODUCTION RELEASE (v12.003 EAB) (1725)

	Yes ◯
PC Time stamp	30 OCT 2020 12:03
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24

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 ●

	Yes ◯
PC Time stamp	31 OCT 2020 22:18
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 4

HEADACHE
- None ⬤
- No interference with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ◯
- Some interference with activity or >2 episodes/24 hours ◯
- Prevents daily activity, requires outpatient IV hydration ◯

CHILLS
- None ⬤
- No interference with activity ◯
- Some interference with activity not requiring medical attention ◯
- Prevents daily activity and requires medical attention ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	01 NOV 2020 19:27
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 5

HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○

NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○

CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	02 NOV 2020 23:37
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

TIMEPOINT	DAY 6

HEADACHE
- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? No ●

	Yes ◯
PC Time stamp	03 NOV 2020 14:00
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

TIMEPOINT	DAY 7

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤

	Yes ◯
PC Time stamp	04 NOV 2020 15:06
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3322341

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

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

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

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3322341
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 04:02:59**
Generated On: 09 Jun 2021 17:05:24

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 13 NOV 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3322341

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag   1

US3322341

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4)　26 Feb 2021 04:03:30

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	24 NOV 2020
Time of assessment *(00:00-23:59)*	15:14 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 15:14
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322341

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?

Yes ●

No ○

Date of examination *(dd MMM yyyy)*

24 NOV 2020

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

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: ▨ (b) (4) ▨ **26 Feb 2021 04:03:30**
Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ●
	No ◯

Collection date *(dd MMM yyyy)*	24 NOV 2020
Collection time *(00:00-23:59)*	15:48 (24 HR)
Collection date and time (derived)	24 NOV 2020 15:48

US3322341

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:03:30**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ⬤

                                                                   No ◯

Continuing Flag   1

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 16:33:02
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 09:43:04
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 03:02:09
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 08:54:03
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 17:39:56
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:24:22
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 14:53:58
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 17:05:21
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 07:46:44
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 09:23:01
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 09:00:12
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 08:17:07
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Date and time of submission	23 FEB 2021 09:38:08
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 08:08:15
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 08:34:25
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 09:54:17
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 08:58:44
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 16:14:54
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 09:13:30
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 10:15:22
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 00:55:42
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 22:12:37
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 15:44:03
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784309

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 JUL 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 313**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 AUG 2021 00:01
Patient Cloud Close Date & Time	11 AUG 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 320

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-0784317

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 AUG 2021 00:01
Patient Cloud Close Date & Time	01 SEP 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 341**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 348**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 355**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 369**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-0784333

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 383**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   **DAY 390**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784341

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 418**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784347

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 432**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 446**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 460

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 481**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   **DAY 495**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

FDA-CBER-2022-1614-0784371

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

FDA-CBER-2022-1614-0784375

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 MAR 2022 00:01
Patient Cloud Close Date & Time	09 MAR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784377

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 537**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 MAR 2022 00:01
Patient Cloud Close Date & Time	23 MAR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 544**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 551**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 558**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-0784385

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 572**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 586**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 MAY 2022 00:01
Patient Cloud Close Date & Time	11 MAY 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 593**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2022 00:01
Patient Cloud Close Date & Time	18 MAY 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ⚪ Yes ⚪

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ⚪ Yes ⚪

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ⚪ Yes ⚪

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ⚪ Yes ⚪

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 607**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-0784399

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2022 00:01
Patient Cloud Close Date & Time	01 JUN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately	○
Date and time of submission		
Patient Cloud Open Date & Time	04 JUN 2022 00:01	
Patient Cloud Close Date & Time	08 JUN 2022 23:59	

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784403

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 642**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

| **TIMEPOINT** | DAY 656 |

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

FDA-CBER-2022-1614-0784415

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784417

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2022 00:01
Patient Cloud Close Date & Time	10 AUG 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 684**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ◯ Yes ◯

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ◯ Yes ◯

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

FDA-CBER-2022-1614-0784423

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 705**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 726**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT   DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-0784439

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2022 00:01
Patient Cloud Close Date & Time	02 NOV 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 768**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2022 00:01
Patient Cloud Close Date & Time	09 NOV 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2022 00:01
Patient Cloud Close Date & Time	23 NOV 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this ◯ message and will call the study clinic immediately
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this ◯ message and will call the study clinic immediately
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2022 00:01
Patient Cloud Close Date & Time	30 NOV 2022 23:59

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT	**DAY 796**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature $\geq$ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2022 00:01
Patient Cloud Close Date & Time	07 DEC 2022 23:59

US3322341

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:05:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	27 FEB 2021 08:08:50

US3322341

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 04:02:59**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3322341

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 25 JAN 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4)   **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3322341

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **24 Mar 2021 22:09:11**

Generated On: 09 Jun 2021 17:05:24

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 FEB 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **24 Mar 2021 22:09:11**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3322341

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 25 MAR 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3322341

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?　　　　　　Yes ●

No ◯

Continuing Flag　　　　　　1

US3322341

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	14 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT4

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **23 Apr 2021 16:34:44**
Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	14 APR 2021
Time of assessment *(00:00-23:59)*	15:51 (24 HR)
Vital Signs Date and Time (derived)	14 APR 2021 15:51
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322341

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

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.

US3322341

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	14 APR 2021
Collection time *(00:00-23:59)*	15:41 (24 HR)
Collection date and time (derived)	14 APR 2021 15:41

US3322341

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?   Yes ●

                                                                                                No ◯

Continuing Flag   1

Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?	Yes ◯
	No ◯

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

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

Comments

If Contact Not Made, please provide Comments _____

US3322341

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?　　　　　　　　　　　　　　　　Yes ◯

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag

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

Type of Contact

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

Has the subject reported symptoms of SARS-COV-2?   Yes ◯
No ◯

US3322341
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:05:24

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

US3322341

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

Form: Visit Date

Data signed: (b) (4) **23 Apr 2021 16:34:43**

Generated On: 09 Jun 2021 17:05:24

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	14 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	UNBLND_DECIDE

US3322341

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

Form: Unblinding

Data signed: (b) (4) **23 Apr 2021 16:34:43**

Generated On: 09 Jun 2021 17:05:24

Date of updated informed consent *(dd MMM yyyy)*	14 APR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ⬤
	No ◯
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ◯
	Amendment 6 or later ⬤
Date of unblinding *(dd MMM yyyy)*	12 FEB 2021
Participant randomization assignment	mRNA-1273 ⬤
	Placebo ◯
Actual Dose 1	mRNA-1273 ⬤
	Placebo ◯
	Not Administered ◯
Actual Dose 2	mRNA-1273 ⬤
	Placebo ◯
	Not Administered ◯
Will participant receive mRNA-1273?	Yes ◯
	No ⬤
Placebo Only Flag	
Continuing with mRNA-1273	

US3322341

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **23 Apr 2021 16:34:43**

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	14 APR 2021
Collection time *(00:00-23:59)*	15:41 (24 HR)
Collection date and time (derived)	14 APR 2021 15:41

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **23 Apr 2021 16:34:43**

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	14 APR 2021
Collection time *(00:00 - 23:59)*	15:36
Collection Date and Time (derived)	14 APR 2021 15:36

US3322341

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **26 Feb 2021 04:02:55**

Generated On: 09 Jun 2021 17:05:24

Did the participant experience any adverse events?   Yes ⬤

No ◯

If Yes, enter details on the Adverse Events form.

US3322341

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **23 Apr 2021 16:34:43**

Generated On: 09 Jun 2021 17:05:24

AEID	USA-US060-2021-MRNA-1273-P30 1000007
Adverse event	POST-OP VAGINAL HEMORRHAGE

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

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

Start date *(dd MMM yyyy)*	13 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	14 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	13 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	14 JAN 2021

Admitted to ICU? Yes ○ No ● Unknown ○

US3322341

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 16:34:43

Generated On: 09 Jun 2021 17:05:24

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

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

SPOKE WITH PATIENT TODAY AT 1351. PATIENT REPORTED OVERNIGHT HOSPITAL ADMISSION TO METHODIST SUGAR LAND HOSPITAL FROM 13JAN2021 THROUGH 14JAN2021. PATIENT HAD POST-OP VAGINAL BLEEDING FROM ROBOTIC LAPAROSCOPIC-ASSISTED HYSTERECTOMY WITH BILATERAL SALPINGECTOMY ON 28DEC2020. PATIENT HAD SCHEDULED HYSTERECTOMY AS TREATMENT FOR UTERINE FIBROIDS AND MENOMETRORRHAGIA. PATIENT WAS RECOVERING WELL, WHEN SHE STARTED EXPERIENCING INCREASED VAGINAL BLEEDING. AFTER INFORMING HER OB/GYN, SHE WAS INSTRUCTED TO MEET HIM IN THE ER FOR FURTHER EVALUATION. UPON EXAMINATION, PATIENT WAS INFORMED THAT INTERNAL SUTURES LOOSENED AND SHE WOULD HAVE TO UNDERGO A REPAIR TO RESOLVE BLEEDING. PATIENT TOLERATED REPAIR WITHOUT INCIDENT AND WAS OBSERVED OVERNIGHT AS A PRECAUTIONARY MEASURE.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **23 Apr 2021 16:34:43**

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	NO FURTHER COMPLICATIONS NOTED. PATIENT WAS DISCHARGED TO HOME IN STABLE CONDITION WITH PROPHYLACTIC ANTIBIOTIC. PATIENT IS DOING WELL WITHOUT ANY COMPLAINTS. PATIENT WILL FOLLOW UP WITH HER OB/GYN AS SCHEDULED. REQUEST FOR MEDICAL RECORDS HAS BEEN OBTAINED.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3322341

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **23 Apr 2021 16:34:43**

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AEID	
Adverse event	ABDOMINAL PAIN DUE TO ABDOMINOPLASTY

Was this a medically-attended AE?	Yes ●
	No ○

Was this a Solicited Adverse Reaction?	Yes ○
	No ●

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

Start date *(dd MMM yyyy)*	22 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?	Yes ●
	No ○

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

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

Is the adverse event serious?	Yes ○
	No ●

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○

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

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ○
- Related ○
- Not Applicable ●

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ○
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ●
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	HYPERTENSION

Was this a medically-attended AE? Yes ⬤ No ◯

Was this a Solicited Adverse Reaction? Yes ◯ No ⬤

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

Start date *(dd MMM yyyy)*	22 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ⬤ No ◯

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

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

Is the adverse event serious? Yes ◯ No ⬤

AE is serious due To (check all that apply)

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

Admitted to ICU? Yes ◯ No ◯ Unknown ◯

Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **23 Apr 2021 16:34:43**

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	●
	Related	○
	Not Applicable	○
Relationship to Study Procedure	Not Related	○
	Related	○
	Not Applicable	●
Action taken with investigational product	None	○
	Dose Delayed	○
	Investigational Product Withdrawn	○
	Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	○
	Not Recovered/Not Resolved	○
	Recovered/Resolved	○
	Recovered/Resolved with Sequelae	○
	Recovering/Resolving	●
	Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **26 Feb 2021 04:02:58**

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

No ◯

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

Name of Medication	ALBUTEROL

Prophylaxis	Yes ◯
	No ⬤

Indication	ASTHMA

Dose per administration	90

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN FEB 2005
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	CHLORPHENIRAMINE MALEATE

Prophylaxis	Yes ⭘
	No ⬤

Indication	SEASONAL ALLERGIES
Dose per administration	4

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ⭘
	Subcutaneous ⭘
	Transdermal ⭘

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2005
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	GARDEN OF LIFE MULTIVITAMIN
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	UNK
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	CONJUGATED LINOLEIC ACID (CLA)
Prophylaxis	Yes ○
	No ●
Indication	WEIGHT LOSS AID
Dose per administration	UNK
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	CHROMIUM PICOLINATE

Prophylaxis	Yes ○
	No ●

Indication	WEIGHT LOSS AID
Dose per administration	UNK

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

If dose unit is Other, specify	UNKNOWN

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

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

Name of Medication	VITAMIN B1
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	UNK
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	UNK
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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EAB) (1725)

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

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

Name of Medication	VITAMIN B3
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	UNK
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	UNK
Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN MAR 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

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

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

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

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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	MORINGA
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	UNK

Dose unit

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

If dose unit is Other, specify	UNK

Frequency

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

If frequency is Other, specify _____

Route of administration

- Oral ●
- Topical ○
- Subcutaneous ○
- Transdermal ○
- Intraocular ○

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	FLAX SEED OIL

Prophylaxis	Yes ⬤
	No ◯

Indication	GENERAL HEALTH

Dose per administration	UNK

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

If dose unit is Other, specify	UNK

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify

Start date *(dd MMM yyyy)* — UN MAR 2020

Start date completely unknown — False

Ongoing? Yes ⬤ No ⬭

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

Was this medication taken for solicited event? Yes ⬭ No ⬤

Separate Dosage Number (derived) — 1

Interval Dosage Unit Number (derived) — 1

Interval Dosage Definition (derived) 802 ⬭ 803 ⬭ 804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: ▨ (b) (4) ▨ **31 Mar 2021 23:59:17**

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

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

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: [(b) (4)] **31 Mar 2021 23:59:17**

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Name of Medication	SEA MOSS

Prophylaxis

Yes ●

No ○

Indication	GENERAL HEALTH
Dose per administration	UNK

Dose unit

mg ○

ug ○

mL ○

g ○

IU ○

tablet ○

capsule ○

puff ○

Other ●

If dose unit is Other, specify	UNK

Frequency

once daily ●

twice daily ○

three times daily ○

four times daily ○

every other day ○

every week ○

every month ○

as needed ○

once ○

unknown ○

other ○

If frequency is Other, specify _____

Route of administration

Oral ●

Topical ○

Subcutaneous ○

Transdermal ○

Intraocular ○

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

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	UN MAY 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

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

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	IV DRIP THERAPY
Prophylaxis	Yes ●
	No ○
Indication	GENERAL HEALTH
Dose per administration	UNK

Dose unit

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

If dose unit is Other, specify	UNK

Frequency

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

If frequency is Other, specify

Route of administration

- Oral ○
- Topical ○
- Subcutaneous ○
- Transdermal ○
- Intraocular ○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN MAR 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	23 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ⬤
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	PSEUDOEPHEDRINE HCI

Prophylaxis	Yes ◯
	No ●

Indication	SINUS HEADACHE SINUS HEADACHE (EXACERBATION OF SEASONAL ALLERGIES)

Dose per administration	10

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

If dose unit is Other, specify	

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

If frequency is Other, specify	EVERY 4 HOURS

Route of administration	Oral ●
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	ACETAMINOPHEN

Prophylaxis

Yes ◯

No ⬤

Indication

SINUS HEADACHE
(EXACERBATION OF SEASONAL
ALLERGIES)

Dose per administration   500

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 SEP 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	IBUPROFEN

Prophylaxis

Yes ◯
No ⬤

Indication	HYSTERECTOMY
Dose per administration	600

Dose unit

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

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	CODEINE/ACETAMINOPHEN

Prophylaxis	Yes ◯
	No ⬤

Indication	HYSTERECTOMY

Dose per administration	5/325

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	METRONIDAZOLE

Prophylaxis	
Yes	◯
No	⬤

Indication	VAGINAL BLEEDING
Dose per administration	500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	14 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	METROPROLOL

Prophylaxis	Yes ◯
	No ⬤

Indication	HYPERTENSION

Dose per administration	25

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
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	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	METHOCARBAMOL

Prophylaxis	Yes	◯
	No	⬤

Indication	ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR/ABDOMINAL PAIN DUE TO ABDOMINOPLASTY

Dose per administration	750

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral	⬤
	Topical	◯
	Subcutaneous	◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	24 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

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Name of Medication	GABAPENTIN

Prophylaxis

Yes ◯
No ⬤

Indication	ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR
Dose per administration	100

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	24 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0784534

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4)   **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

Name of Medication	CLINDAMYCIN

Prophylaxis

Yes ⚪

No ⬤

Indication	ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR
Dose per administration	300

Dose unit

mg ⬤

ug ⚪

mL ⚪

g ⚪

IU ⚪

tablet ⚪

capsule ⚪

puff ⚪

Other ⚪

If dose unit is Other, specify _____

Frequency

once daily ⚪

twice daily ⚪

three times daily ⚪

four times daily ⬤

every other day ⚪

every week ⚪

every month ⚪

as needed ⚪

once ⚪

unknown ⚪

other ⚪

If frequency is Other, specify _____

Route of administration

Oral ⬤

Topical ⚪

Subcutaneous ⚪

Transdermal ⚪

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) **31 Mar 2021 23:59:17**

Generated On: 09 Jun 2021 17:05:24

Name of Medication	CIPROFLOXACIN

Prophylaxis

Yes ⚪

No ⚫

Indication	ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR
Dose per administration	500

Dose unit

mg ⚫

ug ⚪

mL ⚪

g ⚪

IU ⚪

tablet ⚪

capsule ⚪

puff ⚪

Other ⚪

If dose unit is Other, specify _____

Frequency

once daily ⚪

twice daily ⚫

three times daily ⚪

four times daily ⚪

every other day ⚪

every week ⚪

every month ⚪

as needed ⚪

once ⚪

unknown ⚪

other ⚪

If frequency is Other, specify _____

Route of administration

Oral ⚫

Topical ⚪

Subcutaneous ⚪

Transdermal ⚪

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 MAR 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	UNKNOWN DERMAL FILLER

Prophylaxis	Yes ⭘
	No ⬤

Indication	COSMETIC

Dose per administration	1

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	UN UNK 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: ▨ (b) (4) ▨ **26 Feb 2021 04:02:58**

Generated On: 09 Jun 2021 17:05:24

Were any concomitant procedures performed?   Yes ⬤

                                                    No ◯

If yes, please complete Concomitant Procedures form.

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: [(b) (4)] **24 Mar 2021 22:09:11**

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 DEC 2020	ROBOTIC LAPAROSCOPIC-ASSISTED HYSTERECTOMY, BILATERAL SALPINGECTOMY	Other	ELECTIVE
22 FEB 2021	ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR	Other	ELECTIVE PROCEDURE
14 JAN 2021	SUTURE REINFORCEMENT OF THE VAGINAL CUFF FOR HEMOSTASIS	Adverse Event	

Date of dosing discontinuation (dd MMM yyyy) _____

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 _____

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

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 ◯

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ●
	No ○
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ●
	No ○
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/JAN/2021 10:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ⬤ No ◯
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/JAN/2021 18:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ● No ○
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/FEB/2021 12:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (4)
Data signed: (b) (4) **23 Apr 2021 16:34:44**
Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ⬤ No ◯
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 11:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) **23 Apr 2021 16:34:44**

Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ● / No ○
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/MAR/2021 08:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (6)
Data signed: (b) (4) **23 Apr 2021 16:34:44**
Generated On: 09 Jun 2021 17:05:24

SAEID	USA-US060-2021-MRNA-1273-P30 1000007
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ●
	No ○
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 13:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322341 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322341

Form: Participant Creation

Generated On: 09 Jun 2021 17:05:24

Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:11:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'US3322341'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 19:11:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:36:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:32:44

US3322341
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:36:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 19:11:24

US3322341
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:36:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:32:44

US3322341
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'SCRN'	System	14 Sep 2020 13:32:44

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 19:11:25

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '46'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'YEARS'	System	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered '46'	System	14 Sep 2020 13:36:25

US3322341

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Female (F)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '1'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:24

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:24

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

FDA-CBER-2022-1614-0784567

US3322341

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:24

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:05:24
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:55:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:33:11

US3322341

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:24

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:24

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'Sep 2020'	System	14 Sep 2020 13:36:25

US3322341

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:24

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered '2020'	System	14 Sep 2020 13:36:25

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Amendment 3 (3)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:25

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 19:11:24

US3322341
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:05:24
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered '1'	System	14 Sep 2020 13:36:32

US3322341

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:05:24

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 16:59:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:32

US3322341
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:05:24

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User closed query 'Please review medical history source as an attachment in source. This notes Face tight cosmetic procedure. Please review source and reconcile.' (Site from CRA).		31 Mar 2021 22:02:22
Query 'Please review medical history source as an attachment in source. This notes Face tight cosmetic procedure. Please review source and reconcile.' answered with 'added in source and EDC, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:14
User opened query 'Please review medical history source as an attachment in source. This notes Face tight cosmetic procedure. Please review source and reconcile.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:42:03
User closed query 'Per medical history Uterine Fibroids noted 2016; 31Aug20 Face tight-cosmetic procedure noted. Please confirm with source and update accordingly.' (Site from CRA).		31 Mar 2021 15:42:03
Query 'Per medical history Uterine Fibroids noted 2016; 31Aug20 Face tight-cosmetic procedure noted. Please confirm with source and update accordingly.' answered with 'per source, there are no records matching these events, can you point out which lines in source you are referencing? thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:11:38
User opened query 'Per medical history Uterine Fibroids noted 2016; 31Aug20 Face tight-cosmetic procedure noted. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:42:54
DataPoint Verified.		04 Mar 2021 16:40:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:36:36

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
Data point term sent to Coder	System	14 Sep 2020 13:38:16
User entered 'Seasonal Allergies'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1979'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 18:42:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:28
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:37:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1979'	System	14 Sep 2020 13:37:24

US3322341
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1979'	System	14 Sep 2020 13:37:24

US3322341

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:37:24

US3322341
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:37:24

US3322341
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:05:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
Data point term sent to Coder	System	14 Sep 2020 13:38:17
User entered 'Asthma'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		14 Apr 2021 20:32:21
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 19:35:39
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 19:35:39
User entered 'UN UNK 2005' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 19:35:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2007'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:38

US3322341
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	04 Mar 2021 19:35:39
User entered 'Jan 2007'	System	14 Sep 2020 13:37:38

US3322341

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	04 Mar 2021 19:35:39
User entered '2007'	System	14 Sep 2020 13:37:38

US3322341
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:05:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:37:38

US3322341
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:37:38

US3322341
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:05:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Broken ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
Data point term sent to Coder	System	14 Sep 2020 13:38:17
User entered 'broken left ankle'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2017'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:05:24
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2017'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2017'	System	14 Sep 2020 13:37:55

US3322341
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:05:24
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2017'	System	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2017'	System	14 Sep 2020 13:37:55

US3322341
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2017'	System	14 Sep 2020 13:37:55

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Broken wrist - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:48
Data point term sent to Coder	System	14 Sep 2020 13:38:17
User entered 'broken left wrist'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2013'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2013'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:05:24
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2013'	System	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2013'	System	14 Sep 2020 13:38:13

US3322341
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:05:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2013'	System	14 Sep 2020 13:38:13

Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2013'	System	14 Sep 2020 13:38:13

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Lumbar vertebral fracture, LLT: Lumbar vertebral fracture L1 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:41:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:41:50
Data point term sent to Coder	System	14 Sep 2020 13:39:17
User entered 'L1 fracture'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2017'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2017'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2017'	System	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2017'	System	14 Sep 2020 13:38:29

US3322341

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2017'	System	14 Sep 2020 13:38:29

US3322341
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2017'	System	14 Sep 2020 13:38:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:49
Data point term sent to Coder	System	14 Sep 2020 13:39:18
User entered 'insomnia'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

US3322341

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

US3322341

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

US3322341

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

US3322341

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:37:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:40

US3322341

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	14 Sep 2020 13:38:40

US3322341
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:05:24
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	14 Sep 2020 13:38:40

US3322341
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:38:40

US3322341
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:38:40

US3322341
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:05:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		14 Apr 2021 20:32:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Menstruation irregular, LLT: Irregular menstruation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:43:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 18:43:17
Data point term sent to Coder	System	31 Mar 2021 18:42:38
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 18:42:02
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 18:42:02
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 18:42:02
User entered 'irregular menstruation' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 18:42:02
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menometrorrhagia, LLT: Menometrorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 08:55:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 08:55:45
Data point term sent to Coder	System	02 Feb 2021 15:43:19
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:42:40
User entered 'menometorrhagia' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:42:40

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Menstruation irregular, LLT: Irregular menstruation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:39:49
Data point term sent to Coder	System	14 Sep 2020 13:39:18
User entered 'irregular menstruation'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Feb 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:38:58

US3322341
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:05:24
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Feb 2020'	System	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2020'	System	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:38:58

US3322341
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered empty.	System	14 Sep 2020 13:38:58

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
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) (b) (4)	14 Sep 2020 13:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:40:44
Data point term sent to Coder	System	14 Sep 2020 13:40:19
User entered 'penicillin allergy (hives)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1978'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1994'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:35

US3322341
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1978'	System	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1978'	System	14 Sep 2020 13:39:35

US3322341
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:05:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1994'	System	14 Sep 2020 13:39:35

US3322341
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1994'	System	14 Sep 2020 13:39:35

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Cubital tunnel syndrome, LLT: Cubital tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:22:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:22:28
Data point term sent to Coder	System	14 Sep 2020 13:40:19
User entered 'right elbow cubital tunnel syndrome'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

FDA-CBER-2022-1614-0784670

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:38:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	14 Sep 2020 13:39:59

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Peripheral nerve decompression, LLT: Cubital tunnel release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:40:44
Data point term sent to Coder	System	14 Sep 2020 13:40:20
User entered 'cubital tunnel release surgery'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	14 Sep 2020 13:40:16

US3322341
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	14 Sep 2020 13:40:16

US3322341
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:05:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2005'	System	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2005'	System	14 Sep 2020 13:40:16

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:30:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:30:45
Data point term sent to Coder	System	14 Sep 2020 13:41:21
User entered 'right knee arthroscopic lateral release surgery'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1997'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1997'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1997'	System	14 Sep 2020 13:40:38

US3322341
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1997'	System	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1997'	System	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1997'	System	14 Sep 2020 13:40:38

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:41:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:41:44
Data point term sent to Coder	System	14 Sep 2020 13:41:23
User entered 'right knee pain'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1996'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1997'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1996'	System	14 Sep 2020 13:40:57

US3322341
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1996'	System	14 Sep 2020 13:40:57

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1997'	System	14 Sep 2020 13:40:57

US3322341

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1997'	System	14 Sep 2020 13:40:57

US3322341
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:05:24
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Liposuction, LLT: Liposuction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:41:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:41:43
Data point term sent to Coder	System	14 Sep 2020 13:41:24
User entered 'liposuction'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

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US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:14

US3322341
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2018'	System	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2018'	System	14 Sep 2020 13:41:14

US3322341
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:05:24
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 2018'	System	14 Sep 2020 13:41:14

US3322341
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2018'	System	14 Sep 2020 13:41:14

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:16:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:16:45
Data point term sent to Coder	System	14 Sep 2020 13:42:26
User entered 'bunion on right toe'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

FDA-CBER-2022-1614-0784720

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:39:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:30

US3322341
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:41:30

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
Data point term sent to Coder	System	14 Sep 2020 13:42:28
User entered 'right toe bunion excision'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:41:54

US3322341
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:41:54

US3322341
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:41:54

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:41:54

US3322341
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:41:54

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Malocclusion, LLT: Crossbite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:01:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:01:47
Data point term sent to Coder	System	14 Sep 2020 13:42:30
User entered 'cross bite'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1984'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:27

Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1984'	System	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1984'	System	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:42:27

US3322341
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:42:27

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Facial therapeutic procedures, PT: Jaw operation, LLT: Jaw operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:44:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:44:43
Data point term sent to Coder	System	14 Sep 2020 13:43:31
User entered 'jaw realignment surgery'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		04 Mar 2021 16:40:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:42:44

US3322341
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:42:44

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Jan 1995'	System	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '1995'	System	14 Sep 2020 13:42:44

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4)	03 May 2021 23:13:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:36:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:37:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:37:14
Data point term sent to Coder	System	21 Apr 2021 16:35:49
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
Data point term sent to Coder	System	11 Mar 2021 16:00:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 15:59:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 15:59:50
Data point term sent to Coder	System	11 Mar 2021 15:59:19
User entered 'Exacerbation of Seasonal Allergies'	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	03 May 2021 23:13:32
Query 'Start date is after date of Informed Consent. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	03 May 2021 20:06:06
DataPoint Verified.		22 Apr 2021 17:36:04
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	21 Apr 2021 16:35:32
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	11 Mar 2021 16:00:12
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	11 Mar 2021 15:58:51
User entered '28 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4)	03 May 2021 23:13:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:36:04
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

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Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4)	03 May 2021 23:13:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:36:04
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4)	03 May 2021 23:13:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:36:04
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	11 Mar 2021 16:00:12
User entered '30 Sep 2020'	Elisa Moralez (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4)	03 May 2021 23:13:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:36:04
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered 'Sep 2020'	System	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered '2020'	System	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered 'Sep 2020'	System	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:32
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 16:00:12
User entered '2020'	System	11 Mar 2021 15:58:51
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	11 Mar 2021 15:58:24
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:49:14

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Submucous leiomyoma of uterus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:25:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:25:00
Data point term sent to Coder	System	12 Mar 2021 22:44:28
User entered 'Uterine fibroid (submucosal leiomyoma)'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'un Feb 2020'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered '28 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
DataPoint Verified.		31 Mar 2021 15:43:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Feb 2020'	System	12 Mar 2021 22:43:51

US3322341
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2020'	System	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Dec 2020'	System	12 Mar 2021 22:43:51

US3322341
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 17:05:24

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2020'	System	12 Mar 2021 22:43:51

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Skin cosmetic procedure, LLT: Skin cosmetic procedure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:15:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:15:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
Data point term sent to Coder	System	31 Mar 2021 21:28:14
User entered 'Face Tightening Cosmetic Procedure, elective'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:05:24
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
User entered '31 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
User entered '0'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
User entered '31 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:05:24
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 22:02:15
User entered '0'	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Aug 2020'	System	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2020'	System	31 Mar 2021 21:28:01

US3322341

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:24

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered 'Aug 2020'	System	31 Mar 2021 21:28:01

US3322341
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 17:05:24
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:57:37
User entered '2020'	System	31 Mar 2021 21:28:01

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '14:30'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered '12 Sep 2020 14:30'	System	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '63' in	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14
DataPoint set to visible.	System	14 Sep 2020 13:36:32

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '128.4' lb	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14
DataPoint set to visible.	System	14 Sep 2020 13:36:32

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered '22.79260'	System	14 Sep 2020 13:45:14
DataPoint set to visible.	System	14 Sep 2020 13:36:32

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'kg/m2'	System	14 Sep 2020 13:45:14
DataPoint set to visible.	System	14 Sep 2020 13:36:32

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '97.7' F	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '68'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'bpm'	System	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '16'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'breaths/min'	System	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '104'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'mmHg'	System	14 Sep 2020 13:45:14

US3322341

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:05:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '68'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered 'mmHg'	System	14 Sep 2020 13:45:14

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47

US3322341
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47

US3322341
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:06:15
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:23

US3322341

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:06:15
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:23

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:24

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:34

US3322341

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Urine (URINE)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Negative (NEGATIVE)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:07:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:45:47

US3322341
Folder: Screening
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User entered empty.	System	14 Sep 2020 13:45:47

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:05:24
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:05:24
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Driver for a meal prep kitchen; will see 6 people at work (everyone wears face masks & social distance)'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:05:24
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '1'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:05:24
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:23:47
DataPoint Verified.		04 Mar 2021 17:08:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '1-2x a week eat out; 7 days a week goes to gym; grocery shopping 7x a week; sees friends 1-2x a week usually less than 10 people at a time goes to coffee shop 3x week'	Frances Saubon (b) (4) (b) (4)	14 Sep 2020 13:46:30

US3322341
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:55:32

US3322341

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:55:32

US3322341
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 13:55:32

US3322341
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'VISIT1'	System	02 Oct 2020 13:55:32

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 21:12:46

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '116264'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 21:12:46

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 21:12:46

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:58:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:58:19

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 13:58:19

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:58:19

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 13:58:19

US3322341

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:11:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 13:58:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:06:54

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '63' in	(b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '125.7' lb	(b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '63' in	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:05:24
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '125.7' lb	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Pre-Dose (PREDOSE)'		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:00:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 13:59:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 13:59:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '15:30' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1 Oct 2020 15:30'	System	02 Oct 2020 14:00:04
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Oct 2020 14:00:10
User entered '99.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Oct 2020 14:00:04
User entered '99.4' (non-conformant).	(b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '89' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'bpm'	System	02 Oct 2020 14:00:04
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '15' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'breaths/min'	System	02 Oct 2020 14:00:04
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '124' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	02 Oct 2020 14:00:04
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '85' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:04
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	02 Oct 2020 14:00:04
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '63' in	(b) (4) (b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:05:24
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '125.7' lb	(b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Post-Dose (POSTDOSE)'		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 14:00:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 14:00:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:57
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 13:59:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '17:37' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1 Oct 2020 17:37'	System	02 Oct 2020 14:00:57
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '99.0' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '78' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:05:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'bpm'	System	02 Oct 2020 14:00:57
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'breaths/min'	System	02 Oct 2020 14:00:57
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '133' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	02 Oct 2020 14:00:57
User entered empty.	System	02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:00:57
User entered empty.		02 Oct 2020 13:59:15

US3322341

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	02 Oct 2020 14:00:57
User entered empty.	System	02 Oct 2020 13:59:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:01:54

US3322341

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:01:54

US3322341
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Urine (URINE)'	(b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:13:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:14

US3322341

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered empty.	System	02 Oct 2020 14:02:14

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 22:10:17

US3322341

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:14:57
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	05 Nov 2020 21:28:28
User entered '01 Oct 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	05 Nov 2020 21:25:51
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 17:55:46
User entered '1 Oct 2020'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '17:02'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '01 Oct 2020 17:02'	System	05 Nov 2020 21:25:51
User entered '1 Oct 2020 17:02'	System	01 Oct 2020 22:10:17

US3322341
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:05:24

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 22:10:17

US3322341

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:10
User entered 'ONCE'	System	01 Oct 2020 22:10:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 22:10:17

FDA-CBER-2022-1614-0784916

US3322341

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:35

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:35

US3322341

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '16:24'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:35

US3322341

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1 Oct 2020 16:24'	System	02 Oct 2020 14:02:35

US3322341

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:52

US3322341

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		02 Oct 2020 14:02:52

US3322341
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:05:24
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '16:20'	(b) (4), (b) (6)	02 Oct 2020 14:02:52

FDA-CBER-2022-1614-0784924

US3322341

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1 Oct 2020 16:20'	System	02 Oct 2020 14:02:52

US3322341

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		02 Oct 2020 14:02:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:52

FDA-CBER-2022-1614-0784927

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:52

US3322341

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered empty.	System	02 Oct 2020 14:02:52

US3322341
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:14:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:57

US3322341

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	02 Oct 2020 14:02:57

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:38:36', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d058601-813e-405d-81c5-6df7df1c5fec'	System	01 Oct 2020 22:39:10
User entered 'Yes (Y)'	System	01 Oct 2020 22:39:10

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:38:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d058601-813e-405d-81c5-6df7df1c5fec'	System	01 Oct 2020 22:39:10
User entered '99.0'	System	01 Oct 2020 22:39:10

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:38:55', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d058601-813e-405d-81c5-6df7df1c5fec'	System	01 Oct 2020 22:39:10
User entered 'No (N)'	System	01 Oct 2020 22:39:10

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:39:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d058601-813e-405d-81c5-6df7df1c5fec'	System	01 Oct 2020 22:39:10
User entered '01 Oct 2020 17:39'	System	01 Oct 2020 22:39:10

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 17:22'	System	01 Oct 2020 22:10:17

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 19:52'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:58:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '456cfcf6-823a-42bb-a1c5-edd581fa1409'	System	02 Oct 2020 02:58:36
User entered 'Yes (Y)'	System	02 Oct 2020 02:58:36

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:58:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '456cfcf6-823a-42bb-a1c5-edd581fa1409'	System	02 Oct 2020 02:58:36
User entered '101.9'	System	02 Oct 2020 02:58:36

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:58:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '456cfcf6-823a-42bb-a1c5-edd581fa1409'	System	02 Oct 2020 02:58:36
User entered 'No (N)'	System	02 Oct 2020 02:58:36

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:58:34', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '456cfcf6-823a-42bb-a1c5-edd581fa1409'	System	02 Oct 2020 02:58:36
User entered '01 Oct 2020 21:58'	System	02 Oct 2020 02:58:36

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 20:47'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 2'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9eb4f746-9623-4b92-81ff-96ed2951322a'	System	03 Oct 2020 02:27:31
User entered 'Yes (Y)'	System	03 Oct 2020 02:27:31

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:14', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9eb4f746-9623-4b92-81ff-96ed2951322a'	System	03 Oct 2020 02:27:31
User entered '99.3'	System	03 Oct 2020 02:27:31

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9eb4f746-9623-4b92-81ff-96ed2951322a'	System	03 Oct 2020 02:27:31
User entered 'No (N)'	System	03 Oct 2020 02:27:31

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US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:26', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9eb4f746-9623-4b92-81ff-96ed2951322a'	System	03 Oct 2020 02:27:31
User entered '02 Oct 2020 21:27'	System	03 Oct 2020 02:27:31

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 3'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:07:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f562e66b-1936-4dcc-8d20-e575e494fe4d'	System	04 Oct 2020 03:08:02
User entered 'Yes (Y)'	System	04 Oct 2020 03:08:02

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:07:50', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f562e66b-1936-4dcc-8d20-e575e494fe4d'	System	04 Oct 2020 03:08:02
User entered '98.5'	System	04 Oct 2020 03:08:02

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:07:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f562e66b-1936-4dcc-8d20-e575e494fe4d'	System	04 Oct 2020 03:08:02
User entered 'No (N)'	System	04 Oct 2020 03:08:02

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:07:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f562e66b-1936-4dcc-8d20-e575e494fe4d'	System	04 Oct 2020 03:08:02
User entered '03 Oct 2020 22:07'	System	04 Oct 2020 03:08:02

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 4'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:10', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6d754ab-b96d-4c48-922a-b043cd83c6f3'	System	05 Oct 2020 03:26:24
User entered 'Yes (Y)'	System	05 Oct 2020 03:26:24

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6d754ab-b96d-4c48-922a-b043cd83c6f3'	System	05 Oct 2020 03:26:24
User entered '98.5'	System	05 Oct 2020 03:26:24

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:19', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6d754ab-b96d-4c48-922a-b043cd83c6f3'	System	05 Oct 2020 03:26:24
User entered 'No (N)'	System	05 Oct 2020 03:26:24

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6d754ab-b96d-4c48-922a-b043cd83c6f3'	System	05 Oct 2020 03:26:24
User entered '04 Oct 2020 22:26'	System	05 Oct 2020 03:26:24

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 5'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27318789-efde-4468-85b2-db9aa7a286fb'	System	05 Oct 2020 18:40:31
User entered 'Yes (Y)'	System	05 Oct 2020 18:40:31

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27318789-efde-4468-85b2-db9aa7a286fb'	System	05 Oct 2020 18:40:31
User entered '97.8'	System	05 Oct 2020 18:40:31

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27318789-efde-4468-85b2-db9aa7a286fb'	System	05 Oct 2020 18:40:31
User entered 'No (N)'	System	05 Oct 2020 18:40:31

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27318789-efde-4468-85b2-db9aa7a286fb'	System	05 Oct 2020 18:40:31
User entered '05 Oct 2020 13:40'	System	05 Oct 2020 18:40:31

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 6'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:07:10', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'cabc0df7-913e-4cd5-8c93-c91e9ecf5ecb'	System	06 Oct 2020 20:07:41
User entered 'Yes (Y)'	System	06 Oct 2020 20:07:41

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:07:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'cabc0df7-913e-4cd5-8c93-c91e9ecf5ecb'	System	06 Oct 2020 20:07:41
User entered '97.5'	System	06 Oct 2020 20:07:41

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:07:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'cabc0df7-913e-4cd5-8c93-c91e9ecf5ecb'	System	06 Oct 2020 20:07:41
User entered 'No (N)'	System	06 Oct 2020 20:07:41

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:07:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'cabc0df7-913e-4cd5-8c93-c91e9ecf5ecb'	System	06 Oct 2020 20:07:41
User entered '06 Oct 2020 15:07'	System	06 Oct 2020 20:07:41

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 7'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:28', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a8268337-adc6-44e9-8a02-2e025ccd46b8'	System	08 Oct 2020 00:09:45
User entered 'Yes (Y)'	System	08 Oct 2020 00:09:45

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a8268337-adc6-44e9-8a02-2e025ccd46b8'	System	08 Oct 2020 00:09:45
User entered '98.0'	System	08 Oct 2020 00:09:45

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:38', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a8268337-adc6-44e9-8a02-2e025ccd46b8'	System	08 Oct 2020 00:09:45
User entered 'No (N)'	System	08 Oct 2020 00:09:45

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US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:40', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a8268337-adc6-44e9-8a02-2e025ccd46b8'	System	08 Oct 2020 00:09:45
User entered '07 Oct 2020 19:09'	System	08 Oct 2020 00:09:45

US3322341

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:39:17', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ce8aeaff-806b-49f2-ab66-5bbb8d3b233d'	System	01 Oct 2020 22:40:25
User entered 'None (1)'	System	01 Oct 2020 22:40:25

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:39:52', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ce8aeaff-806b-49f2-ab66-5bbb8d3b233d'	System	01 Oct 2020 22:40:25
User entered 'No (N)'	System	01 Oct 2020 22:40:25

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ce8aeaff-806b-49f2-ab66-5bbb8d3b233d'	System	01 Oct 2020 22:40:25
User entered 'No (N)'	System	01 Oct 2020 22:40:25

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:19', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ce8aeaff-806b-49f2-ab66-5bbb8d3b233d'	System	01 Oct 2020 22:40:25
User entered 'None (1)'	System	01 Oct 2020 22:40:25

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ce8aeaff-806b-49f2-ab66-5bbb8d3b233d'	System	01 Oct 2020 22:40:25
User entered '01 Oct 2020 17:40'	System	01 Oct 2020 22:40:25

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 17:22'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 19:52'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:58:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4bb87541-6df2-4e01-bc38-c7ebdea149f6'	System	02 Oct 2020 02:59:37
User entered 'None (1)'	System	02 Oct 2020 02:59:37

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:59:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4bb87541-6df2-4e01-bc38-c7ebdea149f6'	System	02 Oct 2020 02:59:37
User entered 'No (N)'	System	02 Oct 2020 02:59:37

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:59:12', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4bb87541-6df2-4e01-bc38-c7ebdea149f6'	System	02 Oct 2020 02:59:37
User entered 'No (N)'	System	02 Oct 2020 02:59:37

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:59:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4bb87541-6df2-4e01-bc38-c7ebdea149f6'	System	02 Oct 2020 02:59:37
User entered 'None (1)'	System	02 Oct 2020 02:59:37

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:59:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4bb87541-6df2-4e01-bc38-c7ebdea149f6'	System	02 Oct 2020 02:59:37
User entered '01 Oct 2020 21:59'	System	02 Oct 2020 02:59:37

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 20:47'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 2'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '33358359-7403-45de-8cac-b4405b3b7582'	System	03 Oct 2020 02:28:17
User entered 'None (1)'	System	03 Oct 2020 02:28:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '33358359-7403-45de-8cac-b4405b3b7582'	System	03 Oct 2020 02:28:17
User entered 'No (N)'	System	03 Oct 2020 02:28:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:27:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '33358359-7403-45de-8cac-b4405b3b7582'	System	03 Oct 2020 02:28:17
User entered 'No (N)'	System	03 Oct 2020 02:28:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '33358359-7403-45de-8cac-b4405b3b7582'	System	03 Oct 2020 02:28:17
User entered 'None (1)'	System	03 Oct 2020 02:28:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:14', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '33358359-7403-45de-8cac-b4405b3b7582'	System	03 Oct 2020 02:28:17
User entered '02 Oct 2020 21:28'	System	03 Oct 2020 02:28:17

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 3'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '72e372cc-13dc-4a72-8e80-d165684de92c'	System	04 Oct 2020 03:08:31
User entered 'None (1)'	System	04 Oct 2020 03:08:31

FDA-CBER-2022-1614-0785013

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:12', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '72e372cc-13dc-4a72-8e80-d165684de92c'	System	04 Oct 2020 03:08:31
User entered 'No (N)'	System	04 Oct 2020 03:08:31

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:16', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '72e372cc-13dc-4a72-8e80-d165684de92c'	System	04 Oct 2020 03:08:31
User entered 'No (N)'	System	04 Oct 2020 03:08:31

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '72e372cc-13dc-4a72-8e80-d165684de92c'	System	04 Oct 2020 03:08:31
User entered 'None (1)'	System	04 Oct 2020 03:08:31

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:26', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '72e372cc-13dc-4a72-8e80-d165684de92c'	System	04 Oct 2020 03:08:31
User entered '03 Oct 2020 22:08'	System	04 Oct 2020 03:08:31

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 4'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:28', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dfcd98c6-1ea2-4689-b4ef-708d8a8ae113'	System	05 Oct 2020 03:26:48
User entered 'None (1)'	System	05 Oct 2020 03:26:48

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dfcd98c6-1ea2-4689-b4ef-708d8a8ae113'	System	05 Oct 2020 03:26:48
User entered 'No (N)'	System	05 Oct 2020 03:26:48

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:38', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dfcd98c6-1ea2-4689-b4ef-708d8a8ae113'	System	05 Oct 2020 03:26:48
User entered 'No (N)'	System	05 Oct 2020 03:26:48

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dfcd98c6-1ea2-4689-b4ef-708d8a8ae113'	System	05 Oct 2020 03:26:48
User entered 'None (1)'	System	05 Oct 2020 03:26:48

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dfcd98c6-1ea2-4689-b4ef-708d8a8ae113'	System	05 Oct 2020 03:26:48
User entered '04 Oct 2020 22:26'	System	05 Oct 2020 03:26:48

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 5'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:32', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a0ce7879-9c9d-42b7-8e77-2fe2b7ba23b2'	System	05 Oct 2020 18:40:52
User entered 'None (1)'	System	05 Oct 2020 18:40:52

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:36', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a0ce7879-9c9d-42b7-8e77-2fe2b7ba23b2'	System	05 Oct 2020 18:40:52
User entered 'No (N)'	System	05 Oct 2020 18:40:52

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a0ce7879-9c9d-42b7-8e77-2fe2b7ba23b2'	System	05 Oct 2020 18:40:52
User entered 'No (N)'	System	05 Oct 2020 18:40:52

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:44', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a0ce7879-9c9d-42b7-8e77-2fe2b7ba23b2'	System	05 Oct 2020 18:40:52
User entered 'None (1)'	System	05 Oct 2020 18:40:52

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a0ce7879-9c9d-42b7-8e77-2fe2b7ba23b2'	System	05 Oct 2020 18:40:52
User entered '05 Oct 2020 13:40'	System	05 Oct 2020 18:40:52

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 6'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:07:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcae7985-e545-4f6c-9e3f-49d42ef2052b'	System	06 Oct 2020 20:08:28
User entered 'None (1)'	System	06 Oct 2020 20:08:28

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcae7985-e545-4f6c-9e3f-49d42ef2052b'	System	06 Oct 2020 20:08:28
User entered 'No (N)'	System	06 Oct 2020 20:08:28

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcae7985-e545-4f6c-9e3f-49d42ef2052b'	System	06 Oct 2020 20:08:28
User entered 'No (N)'	System	06 Oct 2020 20:08:28

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:16', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcae7985-e545-4f6c-9e3f-49d42ef2052b'	System	06 Oct 2020 20:08:28
User entered 'None (1)'	System	06 Oct 2020 20:08:28

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcae7985-e545-4f6c-9e3f-49d42ef2052b'	System	06 Oct 2020 20:08:28
User entered '06 Oct 2020 15:08'	System	06 Oct 2020 20:08:28

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 7'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3d74dec-8f0c-4145-b34e-0ad070d08b6b'	System	08 Oct 2020 00:10:05
User entered 'None (1)'	System	08 Oct 2020 00:10:05

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3d74dec-8f0c-4145-b34e-0ad070d08b6b'	System	08 Oct 2020 00:10:05
User entered 'No (N)'	System	08 Oct 2020 00:10:05

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3d74dec-8f0c-4145-b34e-0ad070d08b6b'	System	08 Oct 2020 00:10:05
User entered 'No (N)'	System	08 Oct 2020 00:10:05

US3322341

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:57', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3d74dec-8f0c-4145-b34e-0ad070d08b6b'	System	08 Oct 2020 00:10:05
User entered 'None (1)'	System	08 Oct 2020 00:10:05

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:09:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3d74dec-8f0c-4145-b34e-0ad070d08b6b'	System	08 Oct 2020 00:10:05
User entered '07 Oct 2020 19:09'	System	08 Oct 2020 00:10:05

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:36', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:53', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:40:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:41:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'None (0)'	System	01 Oct 2020 22:41:37

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:41:20', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered 'No (N)'	System	01 Oct 2020 22:41:37

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T17:41:33', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0e33f1ee-093e-4e93-9a9d-9bbcfd8b227a'	System	01 Oct 2020 22:41:37
User entered '01 Oct 2020 17:41'	System	01 Oct 2020 22:41:37

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 17:22'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 19:52'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T21:59:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:00:46

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'None (0)'	System	02 Oct 2020 03:00:46

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'None (0)'	System	02 Oct 2020 03:00:46

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'None (0)'	System	02 Oct 2020 03:00:46

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'None (0)'	System	02 Oct 2020 03:00:46

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'None (0)'	System	02 Oct 2020 03:00:46

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered 'No (N)'	System	02 Oct 2020 03:00:46

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-01T22:00:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ddc4ac0a-cfc2-49a8-93c8-ee82a066557b'	System	02 Oct 2020 03:00:46
User entered '01 Oct 2020 22:00'	System	02 Oct 2020 03:00:46

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Oct 2020 20:47'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 2'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:38', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:40', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'None (0)'	System	03 Oct 2020 02:28:52

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered 'No (N)'	System	03 Oct 2020 02:28:52

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-02T21:28:49', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '9acdd29a-6987-4353-93f0-1d5cd32ad3f3'	System	03 Oct 2020 02:28:52
User entered '02 Oct 2020 21:28'	System	03 Oct 2020 02:28:52

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 3'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:08:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:09:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:09:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'None (0)'	System	04 Oct 2020 03:09:15

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:09:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered 'No (N)'	System	04 Oct 2020 03:09:15

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-03T22:09:11', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dad51c2b-fae7-4c4d-8b5a-ab01257a1a27'	System	04 Oct 2020 03:09:15
User entered '03 Oct 2020 22:09'	System	04 Oct 2020 03:09:15

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 4'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:49', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:26:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:06', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'None (0)'	System	05 Oct 2020 03:27:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:12', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered 'No (N)'	System	05 Oct 2020 03:27:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-04T22:27:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3cc17ef8-5ed4-4a60-aac9-c5843977f6e9'	System	05 Oct 2020 03:27:17
User entered '04 Oct 2020 22:27'	System	05 Oct 2020 03:27:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 5'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:55', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:40:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:06', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'None (0)'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered 'No (N)'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-05T13:41:16', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dc704c48-0db4-4dae-87ae-9de1e5186622'	System	05 Oct 2020 18:41:21
User entered '05 Oct 2020 13:41'	System	05 Oct 2020 18:41:21

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 6'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:32', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:49', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:08:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'None (0)'	System	06 Oct 2020 20:09:16

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:09:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered 'No (N)'	System	06 Oct 2020 20:09:16

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-06T15:09:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3b713ae3-9787-4c09-8fe0-a17bb83767dd'	System	06 Oct 2020 20:09:16
User entered '06 Oct 2020 15:09'	System	06 Oct 2020 20:09:16

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	01 Oct 2020 22:10:17
User entered 'Day 7'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:05', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:10', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:16', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'None (0)'	System	08 Oct 2020 00:10:32

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered 'No (N)'	System	08 Oct 2020 00:10:32

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-07T19:10:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '458c595b-fc9d-4f90-8a60-edd3600685f9'	System	08 Oct 2020 00:10:32
User entered '07 Oct 2020 19:10'	System	08 Oct 2020 00:10:32

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 22:10:17

US3322341

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 22:10:17

US3322341

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:15:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 19:23:35

US3322341

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:15:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '9 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 19:23:35

US3322341

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:15:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 19:23:35

US3322341
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:15:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 19:23:35

US3322341
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:15:54
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 19:23:50

US3322341
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	09 Oct 2020 19:23:50

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:16:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:39:02

FDA-CBER-2022-1614-0785146

US3322341

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:16:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '15 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:39:02

US3322341

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:16:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:39:02

US3322341

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:16:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:39:02

US3322341
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:16:31
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:39:06

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	16 Oct 2020 13:39:06

US3322341

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:17:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:09:29

US3322341

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:17:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '22 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:09:29

US3322341
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:17:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:09:29

US3322341
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:17:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:09:29

US3322341

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:17:46
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:09:37

US3322341
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	23 Oct 2020 14:09:37

Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:52:28

FDA-CBER-2022-1614-0785158

US3322341

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:52:28

US3322341

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:52:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'VISIT2'	System	29 Oct 2020 21:52:28

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Pre-Dose (PREDOSE)'		29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4)	29 Oct 2020 21:53:31
	(b) (4), (b) (6)	

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '14:45'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '29 Oct 2020 14:45'	System	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '70'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:05:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'bpm'	System	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'breaths/min'	System	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '139'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '91'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	29 Oct 2020 21:53:31

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Post-Dose (POSTDOSE)'		29 Oct 2020 21:54:03

US3322341
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:05:24
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '16:40'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '29 Oct 2020 16:40'	System	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '85'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:05:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'bpm'	System	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'breaths/min'	System	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '117'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	29 Oct 2020 21:54:03

US3322341

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:19:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '77'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:03

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:05:24
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	29 Oct 2020 21:54:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:13

FDA-CBER-2022-1614-0785194

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:13

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

US3322341
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

US3322341
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

US3322341
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

FDA-CBER-2022-1614-0785200

US3322341
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

US3322341

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:05:24

Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:25

US3322341
Folder: Visit 2 Day 29 (1)
Form: Pregnancy Test
Generated On: 09 Jun 2021 17:05:24
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered empty.	System	29 Oct 2020 21:54:25

US3322341
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

US3322341
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

US3322341

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

US3322341
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'MRNA-1273 OR PLACEBO'	System	29 Oct 2020 21:14:09

US3322341

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '16:06'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

FDA-CBER-2022-1614-0785209

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '29 Oct 2020 16:06'	System	29 Oct 2020 21:14:09

FDA-CBER-2022-1614-0785210

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 21:14:09

US3322341
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:05:24
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:20:53
User entered 'ONCE'	System	29 Oct 2020 21:14:09

US3322341

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'INTRAMUSCULAR'	System	29 Oct 2020 21:14:09

US3322341

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered '15:35'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:44

US3322341

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '29 Oct 2020 15:35'	System	29 Oct 2020 21:54:44

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '15:27'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '29 Oct 2020 15:27'	System	29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:24

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:06

FDA-CBER-2022-1614-0785225

US3322341

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered empty.	System	29 Oct 2020 21:55:06

US3322341

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:21:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:45

US3322341

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	29 Oct 2020 21:55:45

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'd45a9c0a-4cc4-4c78-8a43-84fd87e72ca1'	System	29 Oct 2020 21:41:20
User entered 'Yes (Y)'	System	29 Oct 2020 21:41:20

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'd45a9c0a-4cc4-4c78-8a43-84fd87e72ca1'	System	29 Oct 2020 21:41:20
User entered '99.0'	System	29 Oct 2020 21:41:20

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:11', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'd45a9c0a-4cc4-4c78-8a43-84fd87e72ca1'	System	29 Oct 2020 21:41:20
User entered 'No (N)'	System	29 Oct 2020 21:41:20

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:14', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'd45a9c0a-4cc4-4c78-8a43-84fd87e72ca1'	System	29 Oct 2020 21:41:20
User entered '29 Oct 2020 16:41'	System	29 Oct 2020 21:41:20

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 16:26'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 18:56'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:00:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dda6a831-3ebe-4d67-9994-9384d4a04b10'	System	30 Oct 2020 02:01:16
User entered 'Yes (Y)'	System	30 Oct 2020 02:01:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:00:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dda6a831-3ebe-4d67-9994-9384d4a04b10'	System	30 Oct 2020 02:01:16
User entered '99.0'	System	30 Oct 2020 02:01:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:02', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dda6a831-3ebe-4d67-9994-9384d4a04b10'	System	30 Oct 2020 02:01:16
User entered 'No (N)'	System	30 Oct 2020 02:01:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dda6a831-3ebe-4d67-9994-9384d4a04b10'	System	30 Oct 2020 02:01:16
User entered '29 Oct 2020 21:01'	System	30 Oct 2020 02:01:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 19:51'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 2'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:02:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ff61cb38-5136-4e59-a3c6-c014924b6f02'	System	30 Oct 2020 17:04:23
User entered 'Yes (Y)'	System	30 Oct 2020 17:04:23

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:02:50', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ff61cb38-5136-4e59-a3c6-c014924b6f02'	System	30 Oct 2020 17:04:23
User entered '98.7'	System	30 Oct 2020 17:04:23

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:02:53', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ff61cb38-5136-4e59-a3c6-c014924b6f02'	System	30 Oct 2020 17:04:23
User entered 'No (N)'	System	30 Oct 2020 17:04:23

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:02:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ff61cb38-5136-4e59-a3c6-c014924b6f02'	System	30 Oct 2020 17:04:23
User entered '30 Oct 2020 12:02'	System	30 Oct 2020 17:04:23

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 3'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:13:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'db901a02-a5d4-47a2-8928-bf273b98ac4a'	System	01 Nov 2020 03:14:19
User entered 'Yes (Y)'	System	01 Nov 2020 03:14:19

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:14:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'db901a02-a5d4-47a2-8928-bf273b98ac4a'	System	01 Nov 2020 03:14:19
User entered '97.9'	System	01 Nov 2020 03:14:19

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:14:12', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'db901a02-a5d4-47a2-8928-bf273b98ac4a'	System	01 Nov 2020 03:14:19
User entered 'No (N)'	System	01 Nov 2020 03:14:19

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:14:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'db901a02-a5d4-47a2-8928-bf273b98ac4a'	System	01 Nov 2020 03:14:19
User entered '31 Oct 2020 22:14'	System	01 Nov 2020 03:14:19

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 4'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:26:36', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcc8b359-51df-4c3e-bd1f-efd652c689ed'	System	02 Nov 2020 01:26:54
User entered 'Yes (Y)'	System	02 Nov 2020 01:26:54

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:26:42', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcc8b359-51df-4c3e-bd1f-efd652c689ed'	System	02 Nov 2020 01:26:54
User entered '98.4'	System	02 Nov 2020 01:26:54

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:26:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcc8b359-51df-4c3e-bd1f-efd652c689ed'	System	02 Nov 2020 01:26:54
User entered 'No (N)'	System	02 Nov 2020 01:26:54

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:26:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'dcc8b359-51df-4c3e-bd1f-efd652c689ed'	System	02 Nov 2020 01:26:54
User entered '01 Nov 2020 19:26'	System	02 Nov 2020 01:26:54

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 5'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:36:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c9bedbf6-2544-4c68-a2e2-7e7aab72681d'	System	03 Nov 2020 05:37:10
User entered 'Yes (Y)'	System	03 Nov 2020 05:37:10

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:36:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c9bedbf6-2544-4c68-a2e2-7e7aab72681d'	System	03 Nov 2020 05:37:10
User entered '98.0'	System	03 Nov 2020 05:37:10

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:02', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c9bedbf6-2544-4c68-a2e2-7e7aab72681d'	System	03 Nov 2020 05:37:10
User entered 'No (N)'	System	03 Nov 2020 05:37:10

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:05', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c9bedbf6-2544-4c68-a2e2-7e7aab72681d'	System	03 Nov 2020 05:37:10
User entered '02 Nov 2020 23:37'	System	03 Nov 2020 05:37:10

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 6'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:58:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3316a66-ed54-474e-96c7-4f121acc90cf'	System	03 Nov 2020 19:59:16
User entered 'Yes (Y)'	System	03 Nov 2020 19:59:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:05', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3316a66-ed54-474e-96c7-4f121acc90cf'	System	03 Nov 2020 19:59:16
User entered '98.1'	System	03 Nov 2020 19:59:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3316a66-ed54-474e-96c7-4f121acc90cf'	System	03 Nov 2020 19:59:16
User entered 'No (N)'	System	03 Nov 2020 19:59:16

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:11', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'b3316a66-ed54-474e-96c7-4f121acc90cf'	System	03 Nov 2020 19:59:16
User entered '03 Nov 2020 13:59'	System	03 Nov 2020 19:59:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 7'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:05:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'e311ea0f-ff45-4307-ac99-807274220ff7'	System	04 Nov 2020 21:06:05
User entered 'Yes (Y)'	System	04 Nov 2020 21:06:05

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:05:53', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'e311ea0f-ff45-4307-ac99-807274220ff7'	System	04 Nov 2020 21:06:05
User entered '97.7'	System	04 Nov 2020 21:06:05

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:05:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'e311ea0f-ff45-4307-ac99-807274220ff7'	System	04 Nov 2020 21:06:05
User entered 'No (N)'	System	04 Nov 2020 21:06:05

US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:05:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'e311ea0f-ff45-4307-ac99-807274220ff7'	System	04 Nov 2020 21:06:05
User entered '04 Nov 2020 15:05'	System	04 Nov 2020 21:06:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

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US3322341

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27ee44a6-cc5f-455c-b687-a2def191d02c'	System	29 Oct 2020 21:41:42
User entered 'None (1)'	System	29 Oct 2020 21:41:42

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27ee44a6-cc5f-455c-b687-a2def191d02c'	System	29 Oct 2020 21:41:42
User entered 'No (N)'	System	29 Oct 2020 21:41:42

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:29', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27ee44a6-cc5f-455c-b687-a2def191d02c'	System	29 Oct 2020 21:41:42
User entered 'No (N)'	System	29 Oct 2020 21:41:42

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:33', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27ee44a6-cc5f-455c-b687-a2def191d02c'	System	29 Oct 2020 21:41:42
User entered 'None (1)'	System	29 Oct 2020 21:41:42

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '27ee44a6-cc5f-455c-b687-a2def191d02c'	System	29 Oct 2020 21:41:42
User entered '29 Oct 2020 16:41'	System	29 Oct 2020 21:41:42

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 16:26'	System	29 Oct 2020 21:14:09

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 18:56'	System	29 Oct 2020 21:14:09

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US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'be86676b-7743-4ba3-b795-9b9572204a52'	System	30 Oct 2020 02:01:38
User entered 'None (1)'	System	30 Oct 2020 02:01:38

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:25', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'be86676b-7743-4ba3-b795-9b9572204a52'	System	30 Oct 2020 02:01:38
User entered 'No (N)'	System	30 Oct 2020 02:01:38

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:28', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'be86676b-7743-4ba3-b795-9b9572204a52'	System	30 Oct 2020 02:01:38
User entered 'No (N)'	System	30 Oct 2020 02:01:38

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'be86676b-7743-4ba3-b795-9b9572204a52'	System	30 Oct 2020 02:01:38
User entered 'None (1)'	System	30 Oct 2020 02:01:38

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:34', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'be86676b-7743-4ba3-b795-9b9572204a52'	System	30 Oct 2020 02:01:38
User entered '29 Oct 2020 21:01'	System	30 Oct 2020 02:01:38

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 19:51'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 2'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f5b875e5-4814-46ac-8975-b14c0fbbc6a2'	System	30 Oct 2020 17:04:47
User entered 'None (1)'	System	30 Oct 2020 17:04:47

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:06', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f5b875e5-4814-46ac-8975-b14c0fbbc6a2'	System	30 Oct 2020 17:04:47
User entered 'No (N)'	System	30 Oct 2020 17:04:47

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:10', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f5b875e5-4814-46ac-8975-b14c0fbbc6a2'	System	30 Oct 2020 17:04:47
User entered 'No (N)'	System	30 Oct 2020 17:04:47

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f5b875e5-4814-46ac-8975-b14c0fbbc6a2'	System	30 Oct 2020 17:04:47
User entered 'None (1)'	System	30 Oct 2020 17:04:47

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:19', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'f5b875e5-4814-46ac-8975-b14c0fbbc6a2'	System	30 Oct 2020 17:04:47
User entered '30 Oct 2020 12:03'	System	30 Oct 2020 17:04:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

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US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 3'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:14:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered 'None (1)'	System	01 Nov 2020 03:18:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:14:28', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered 'Yes (Y)'	System	01 Nov 2020 03:18:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:17:57', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered '9'	System	01 Nov 2020 03:18:32

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:05', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered 'Yes (Y)'	System	01 Nov 2020 03:18:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:14', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered '9'	System	01 Nov 2020 03:18:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:23', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered 'None (1)'	System	01 Nov 2020 03:18:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:30', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ee3dc063-634d-47bb-b344-763088b12102'	System	01 Nov 2020 03:18:32
User entered '31 Oct 2020 22:18'	System	01 Nov 2020 03:18:32

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 4'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:26:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2a3cd8ef-b2dc-4ab7-8ba6-adf1ec213852'	System	02 Nov 2020 01:27:27
User entered 'None (1)'	System	02 Nov 2020 01:27:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2a3cd8ef-b2dc-4ab7-8ba6-adf1ec213852'	System	02 Nov 2020 01:27:27
User entered 'No (N)'	System	02 Nov 2020 01:27:27

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2a3cd8ef-b2dc-4ab7-8ba6-adf1ec213852'	System	02 Nov 2020 01:27:27
User entered 'No (N)'	System	02 Nov 2020 01:27:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2a3cd8ef-b2dc-4ab7-8ba6-adf1ec213852'	System	02 Nov 2020 01:27:27
User entered 'None (1)'	System	02 Nov 2020 01:27:27

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US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:25', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2a3cd8ef-b2dc-4ab7-8ba6-adf1ec213852'	System	02 Nov 2020 01:27:27
User entered '01 Nov 2020 19:27'	System	02 Nov 2020 01:27:27

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 5'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d420541-5ccc-4178-b554-1f40b87fb1f7'	System	03 Nov 2020 05:37:27
User entered 'None (1)'	System	03 Nov 2020 05:37:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d420541-5ccc-4178-b554-1f40b87fb1f7'	System	03 Nov 2020 05:37:27
User entered 'No (N)'	System	03 Nov 2020 05:37:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:16', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d420541-5ccc-4178-b554-1f40b87fb1f7'	System	03 Nov 2020 05:37:27
User entered 'No (N)'	System	03 Nov 2020 05:37:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d420541-5ccc-4178-b554-1f40b87fb1f7'	System	03 Nov 2020 05:37:27
User entered 'None (1)'	System	03 Nov 2020 05:37:27

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '4d420541-5ccc-4178-b554-1f40b87fb1f7'	System	03 Nov 2020 05:37:27
User entered '02 Nov 2020 23:37'	System	03 Nov 2020 05:37:27

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 6'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:15', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '57095e00-c4a0-4f49-9101-50b107f69dd3'	System	03 Nov 2020 19:59:32
User entered 'None (1)'	System	03 Nov 2020 19:59:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:18', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '57095e00-c4a0-4f49-9101-50b107f69dd3'	System	03 Nov 2020 19:59:32
User entered 'No (N)'	System	03 Nov 2020 19:59:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '57095e00-c4a0-4f49-9101-50b107f69dd3'	System	03 Nov 2020 19:59:32
User entered 'No (N)'	System	03 Nov 2020 19:59:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:25', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '57095e00-c4a0-4f49-9101-50b107f69dd3'	System	03 Nov 2020 19:59:32
User entered 'None (1)'	System	03 Nov 2020 19:59:32

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '57095e00-c4a0-4f49-9101-50b107f69dd3'	System	03 Nov 2020 19:59:32
User entered '03 Nov 2020 13:59'	System	03 Nov 2020 19:59:32

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 7'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:06', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c3abbf24-e00c-4161-85e9-21830590e9bc'	System	04 Nov 2020 21:06:24
User entered 'None (1)'	System	04 Nov 2020 21:06:24

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:10', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c3abbf24-e00c-4161-85e9-21830590e9bc'	System	04 Nov 2020 21:06:24
User entered 'No (N)'	System	04 Nov 2020 21:06:24

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:14', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c3abbf24-e00c-4161-85e9-21830590e9bc'	System	04 Nov 2020 21:06:24
User entered 'No (N)'	System	04 Nov 2020 21:06:24

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:17', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c3abbf24-e00c-4161-85e9-21830590e9bc'	System	04 Nov 2020 21:06:24
User entered 'None (1)'	System	04 Nov 2020 21:06:24

US3322341

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c3abbf24-e00c-4161-85e9-21830590e9bc'	System	04 Nov 2020 21:06:24
User entered '04 Nov 2020 15:06'	System	04 Nov 2020 21:06:24

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:55', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:41:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:42:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'None (0)'	System	29 Oct 2020 21:42:14

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:42:05', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered 'No (N)'	System	29 Oct 2020 21:42:14

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T16:42:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0ecd1362-f686-488a-84be-fb907419211c'	System	29 Oct 2020 21:42:14
User entered '29 Oct 2020 16:42'	System	29 Oct 2020 21:42:14

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 16:26'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 18:56'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 1, after vaccination (at home)'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:44', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:57', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:01:59', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'None (0)'	System	30 Oct 2020 02:02:11

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:02:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered 'No (N)'	System	30 Oct 2020 02:02:11

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-29T21:02:06', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '041ad9c4-a952-4b18-8314-080104ef4204'	System	30 Oct 2020 02:02:11
User entered '29 Oct 2020 21:02'	System	30 Oct 2020 02:02:11

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '29 Oct 2020 19:51'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:05:24
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 2'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:29', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'No interference with activity (1)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'None (0)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:39', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'None (0)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:42', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'None (0)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'None (0)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'None (0)'	System	30 Oct 2020 17:05:13

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered 'No (N)'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-30T12:03:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '45a8ac36-595b-4d6e-a286-f6320c3faa68'	System	30 Oct 2020 17:05:13
User entered '30 Oct 2020 12:03'	System	30 Oct 2020 17:05:13

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 3'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:39', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:42', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:45', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:50', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'None (0)'	System	01 Nov 2020 03:19:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered 'No (N)'	System	01 Nov 2020 03:19:00

FDA-CBER-2022-1614-0785391

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-10-31T22:18:57', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1fecc456-42b2-4cda-8637-008eff3b976f'	System	01 Nov 2020 03:19:00
User entered '31 Oct 2020 22:18'	System	01 Nov 2020 03:19:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 21:14:09

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 4'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:30', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:32', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:38', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:44', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'None (0)'	System	02 Nov 2020 01:27:51

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered 'No (N)'	System	02 Nov 2020 01:27:51

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-01T19:27:48', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c053cd5f-2a7d-4db6-bec4-76eafba41a46'	System	02 Nov 2020 01:27:51
User entered '01 Nov 2020 19:27'	System	02 Nov 2020 01:27:51

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:05:24
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '01 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 5'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:26', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:30', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:32', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:36', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:38', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'None (0)'	System	03 Nov 2020 05:37:50

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:44', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered 'No (N)'	System	03 Nov 2020 05:37:50

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-02T23:37:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '1f0eedd6-934b-4617-88ea-b9ce85e6dd35'	System	03 Nov 2020 05:37:50
User entered '02 Nov 2020 23:37'	System	03 Nov 2020 05:37:50

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '02 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 6'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:49', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:54', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T13:59:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'None (0)'	System	03 Nov 2020 20:00:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T14:00:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered 'No (N)'	System	03 Nov 2020 20:00:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-03T14:00:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '76bf0eaa-fd08-44ac-a8d6-109ce42840e2'	System	03 Nov 2020 20:00:09
User entered '03 Nov 2020 14:00'	System	03 Nov 2020 20:00:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '03 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
Data entry locked.	System	29 Oct 2020 21:14:09
User entered 'Day 7'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:27', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:35', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:40', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:05:24
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'None (0)'	System	04 Nov 2020 21:07:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered 'No (N)'	System	04 Nov 2020 21:07:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-04T15:06:55', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3409d822-01ac-41ca-b6cc-5853f9013245'	System	04 Nov 2020 21:07:00
User entered '04 Nov 2020 15:06'	System	04 Nov 2020 21:07:00

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '04 Nov 2020 12:00'	System	29 Oct 2020 21:14:09

US3322341

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:24

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:01:29
User entered '05 Nov 2020 11:59'	System	29 Oct 2020 21:14:09

US3322341

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:22:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:26:36

US3322341

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:22:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '5 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:26:36

US3322341

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:22:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:26:36

US3322341
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:22:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:26:36

US3322341

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:26:11

US3322341
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	05 Nov 2020 18:26:11

US3322341

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:23:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:18:42

US3322341
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:23:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:18:42

US3322341
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:23:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:18:42

US3322341

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:23:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:18:42

US3322341

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:23:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:18:46

US3322341
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	13 Nov 2020 15:18:46

US3322341

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:32:01

US3322341

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '19 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:32:01

US3322341

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:32:01

US3322341

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:32:01

US3322341
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:32:08

US3322341
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	20 Nov 2020 15:32:08

US3322341
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:30:55

US3322341

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '24 Nov 2020'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:30:55

US3322341

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:24:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Clinic (Clinic)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:30:55

US3322341
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'VISIT3'	System	24 Nov 2020 22:30:55

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '24 Nov 2020'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '15:14'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '24 Nov 2020 15:14'	System	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '98.8' F	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Oral (Oral)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered empty.	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '76'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'bpm'	System	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '15'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'breaths/min'	System	24 Nov 2020 22:31:35

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '142'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	24 Nov 2020 22:31:35

FDA-CBER-2022-1614-0785473

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '86'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:35

US3322341

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered 'mmHg'	System	24 Nov 2020 22:31:35

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19

US3322341
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19

US3322341

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:45

US3322341

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '24 Nov 2020'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:31:45

US3322341

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:32:05

US3322341

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '24 Nov 2020'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:32:05

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered '15:48'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:32:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '24 Nov 2020 15:48'	System	24 Nov 2020 22:32:05

FDA-CBER-2022-1614-0785483

US3322341
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:25:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	24 Nov 2020 22:32:15

US3322341
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	24 Nov 2020 22:32:15

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-30T16:32:41', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '986d9f86-97e5-4288-8608-e1bff3712e44'	System	30 Nov 2020 22:33:07
User entered 'No (N)'	System	30 Nov 2020 22:33:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-30T16:32:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '986d9f86-97e5-4288-8608-e1bff3712e44'	System	30 Nov 2020 22:33:07
User entered 'No (N)'	System	30 Nov 2020 22:33:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-11-30T16:33:02', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '986d9f86-97e5-4288-8608-e1bff3712e44'	System	30 Nov 2020 22:33:07
User entered '30 Nov 2020 16:33:02'	System	30 Nov 2020 22:33:07

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-05T09:42:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '94a54627-a3ca-45db-8aff-e14dffea0905'	System	05 Dec 2020 15:43:07
User entered 'No (N)'	System	05 Dec 2020 15:43:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-05T09:42:52', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '94a54627-a3ca-45db-8aff-e14dffea0905'	System	05 Dec 2020 15:43:07
User entered 'No (N)'	System	05 Dec 2020 15:43:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-05T09:43:04', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '94a54627-a3ca-45db-8aff-e14dffea0905'	System	05 Dec 2020 15:43:07
User entered '05 Dec 2020 09:43:04'	System	05 Dec 2020 15:43:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-15T03:01:50', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c317ae5d-11fc-4c71-a6cc-9281aab206ae'	System	15 Dec 2020 09:02:13
User entered 'No (N)'	System	15 Dec 2020 09:02:13

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-15T03:02:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c317ae5d-11fc-4c71-a6cc-9281aab206ae'	System	15 Dec 2020 09:02:13
User entered 'No (N)'	System	15 Dec 2020 09:02:13

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-15T03:02:09', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c317ae5d-11fc-4c71-a6cc-9281aab206ae'	System	15 Dec 2020 09:02:13
User entered '15 Dec 2020 03:02:09'	System	15 Dec 2020 09:02:13

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-19T08:53:31', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '88c0813f-f318-4b1a-8e2f-6144ac601eb3'	System	19 Dec 2020 14:54:06
User entered 'No (N)'	System	19 Dec 2020 14:54:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-19T08:53:43', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '88c0813f-f318-4b1a-8e2f-6144ac601eb3'	System	19 Dec 2020 14:54:06
User entered 'No (N)'	System	19 Dec 2020 14:54:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-19T08:54:03', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '88c0813f-f318-4b1a-8e2f-6144ac601eb3'	System	19 Dec 2020 14:54:06
User entered '19 Dec 2020 08:54:03'	System	19 Dec 2020 14:54:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-26T17:39:47', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0edeb470-d726-4827-81d9-3c00c1e0353f'	System	26 Dec 2020 23:39:58
User entered 'No (N)'	System	26 Dec 2020 23:39:58

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-26T17:39:52', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0edeb470-d726-4827-81d9-3c00c1e0353f'	System	26 Dec 2020 23:39:58
User entered 'No (N)'	System	26 Dec 2020 23:39:58

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2020-12-26T17:39:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0edeb470-d726-4827-81d9-3c00c1e0353f'	System	26 Dec 2020 23:39:58
User entered '26 Dec 2020 17:39:56'	System	26 Dec 2020 23:39:58

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785515

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-02T00:23:55', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '5c946c88-fbe4-476a-a2b7-89615d00cd14'	System	02 Jan 2021 06:24:23
User entered 'No (N)'	System	02 Jan 2021 06:24:23

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-02T00:24:17', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '5c946c88-fbe4-476a-a2b7-89615d00cd14'	System	02 Jan 2021 06:24:23
User entered 'No (N)'	System	02 Jan 2021 06:24:23

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-02T00:24:22', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '5c946c88-fbe4-476a-a2b7-89615d00cd14'	System	02 Jan 2021 06:24:23
User entered '02 Jan 2021 00:24:22'	System	02 Jan 2021 06:24:23

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-12T14:53:39', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2b1c4ca4-005a-48cf-a902-c8a95edfa637'	System	12 Jan 2021 20:54:01
User entered 'No (N)'	System	12 Jan 2021 20:54:01

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-12T14:53:53', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2b1c4ca4-005a-48cf-a902-c8a95edfa637'	System	12 Jan 2021 20:54:01
User entered 'No (N)'	System	12 Jan 2021 20:54:01

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-12T14:53:58', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2b1c4ca4-005a-48cf-a902-c8a95edfa637'	System	12 Jan 2021 20:54:01
User entered '12 Jan 2021 14:53:58'	System	12 Jan 2021 20:54:01

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-18T17:05:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7a0a2c41-f9f0-4ea7-ba28-d679233ab3fc'	System	18 Jan 2021 23:05:30
User entered 'No (N)'	System	18 Jan 2021 23:05:30

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-18T17:05:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7a0a2c41-f9f0-4ea7-ba28-d679233ab3fc'	System	18 Jan 2021 23:05:30
User entered 'No (N)'	System	18 Jan 2021 23:05:30

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-18T17:05:21', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7a0a2c41-f9f0-4ea7-ba28-d679233ab3fc'	System	18 Jan 2021 23:05:30
User entered '18 Jan 2021 17:05:21'	System	18 Jan 2021 23:05:30

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-23T07:46:28', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0d0eee71-b340-4422-a204-a4418d814156'	System	23 Jan 2021 13:46:45
User entered 'No (N)'	System	23 Jan 2021 13:46:45

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-23T07:46:37', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0d0eee71-b340-4422-a204-a4418d814156'	System	23 Jan 2021 13:46:45
User entered 'No (N)'	System	23 Jan 2021 13:46:45

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-23T07:46:44', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '0d0eee71-b340-4422-a204-a4418d814156'	System	23 Jan 2021 13:46:45
User entered '23 Jan 2021 07:46:44'	System	23 Jan 2021 13:46:45

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-30T09:22:46', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2981ef33-b299-4ab4-8135-f08e6922ac7d'	System	30 Jan 2021 15:23:06
User entered 'No (N)'	System	30 Jan 2021 15:23:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-30T09:22:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2981ef33-b299-4ab4-8135-f08e6922ac7d'	System	30 Jan 2021 15:23:06
User entered 'No (N)'	System	30 Jan 2021 15:23:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-01-30T09:23:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '2981ef33-b299-4ab4-8135-f08e6922ac7d'	System	30 Jan 2021 15:23:06
User entered '30 Jan 2021 09:23:01'	System	30 Jan 2021 15:23:06

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-07T08:59:51', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '6d5b40f0-d053-4212-abb7-7b73f07ab4e4'	System	07 Feb 2021 15:00:14
User entered 'No (N)'	System	07 Feb 2021 15:00:14

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-07T09:00:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '6d5b40f0-d053-4212-abb7-7b73f07ab4e4'	System	07 Feb 2021 15:00:14
User entered 'No (N)'	System	07 Feb 2021 15:00:14

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-07T09:00:12', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '6d5b40f0-d053-4212-abb7-7b73f07ab4e4'	System	07 Feb 2021 15:00:14
User entered '07 Feb 2021 09:00:12'	System	07 Feb 2021 15:00:14

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-13T08:16:49', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6fef6d5-7d7a-4ea3-be0b-1defcb3714c3'	System	13 Feb 2021 14:17:11
User entered 'No (N)'	System	13 Feb 2021 14:17:11

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-13T08:16:56', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6fef6d5-7d7a-4ea3-be0b-1defcb3714c3'	System	13 Feb 2021 14:17:11
User entered 'No (N)'	System	13 Feb 2021 14:17:11

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-13T08:17:07', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c6fef6d5-7d7a-4ea3-be0b-1defcb3714c3'	System	13 Feb 2021 14:17:11
User entered '13 Feb 2021 08:17:07'	System	13 Feb 2021 14:17:11

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:06:44

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US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:37:13', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered 'Yes (Y)'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:37:24', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered 'No (N)'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:37:34', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered 'No (N)'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:37:50', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered 'Yes (Y)'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:38:01', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-23T09:38:08', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'fbe5f01d-c58b-4cb4-b3ea-0e03a0dae2ef'	System	23 Feb 2021 15:38:20
User entered '23 Feb 2021 09:38:08'	System	23 Feb 2021 15:38:20

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:02-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '409cb9a4-e937-4469-bd03-b43360234829'	System	27 Feb 2021 14:08:17
User entered 'No (N)'	System	27 Feb 2021 14:08:17

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:06-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '409cb9a4-e937-4469-bd03-b43360234829'	System	27 Feb 2021 14:08:17
User entered 'No (N)'	System	27 Feb 2021 14:08:17

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:15-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '409cb9a4-e937-4469-bd03-b43360234829'	System	27 Feb 2021 14:08:17
User entered '27 Feb 2021 08:08:15'	System	27 Feb 2021 14:08:17

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-06T08:34:12-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '96cd48ad-c7f0-42b5-b12e-6985bc22221d'	System	06 Mar 2021 14:34:28
User entered 'No (N)'	System	06 Mar 2021 14:34:28

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-06T08:34:21-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '96cd48ad-c7f0-42b5-b12e-6985bc22221d'	System	06 Mar 2021 14:34:28
User entered 'No (N)'	System	06 Mar 2021 14:34:28

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-06T08:34:25-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '96cd48ad-c7f0-42b5-b12e-6985bc22221d'	System	06 Mar 2021 14:34:28
User entered '06 Mar 2021 08:34:25'	System	06 Mar 2021 14:34:28

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-13T09:54:02-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3c48b193-0424-4c4c-80b6-3f34b6efc4d6'	System	13 Mar 2021 15:54:19
User entered 'No (N)'	System	13 Mar 2021 15:54:19

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-13T09:54:12-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3c48b193-0424-4c4c-80b6-3f34b6efc4d6'	System	13 Mar 2021 15:54:19
User entered 'No (N)'	System	13 Mar 2021 15:54:19

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-13T09:54:17-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3c48b193-0424-4c4c-80b6-3f34b6efc4d6'	System	13 Mar 2021 15:54:19
User entered '13 Mar 2021 09:54:17'	System	13 Mar 2021 15:54:19

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-20T08:58:35-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a2207b94-fbd9-45ce-9779-dfff48b026a0'	System	20 Mar 2021 13:58:46
User entered 'No (N)'	System	20 Mar 2021 13:58:46

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-20T08:58:39-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a2207b94-fbd9-45ce-9779-dfff48b026a0'	System	20 Mar 2021 13:58:46
User entered 'No (N)'	System	20 Mar 2021 13:58:46

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-20T08:58:44-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'a2207b94-fbd9-45ce-9779-dfff48b026a0'	System	20 Mar 2021 13:58:46
User entered '20 Mar 2021 08:58:44'	System	20 Mar 2021 13:58:46

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-27T16:14:47-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c58e8504-5c57-4128-b90f-194a54752462'	System	27 Mar 2021 21:14:57
User entered 'No (N)'	System	27 Mar 2021 21:14:57

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-27T16:14:51-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c58e8504-5c57-4128-b90f-194a54752462'	System	27 Mar 2021 21:14:57
User entered 'No (N)'	System	27 Mar 2021 21:14:57

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-03-27T16:14:54-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'c58e8504-5c57-4128-b90f-194a54752462'	System	27 Mar 2021 21:14:57
User entered '27 Mar 2021 16:14:54'	System	27 Mar 2021 21:14:57

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-05T09:13:19-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '65d5383f-9f08-40c1-81d1-eb13be7b6fcc'	System	05 Apr 2021 14:13:36
User entered 'No (N)'	System	05 Apr 2021 14:13:36

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-05T09:13:26-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '65d5383f-9f08-40c1-81d1-eb13be7b6fcc'	System	05 Apr 2021 14:13:36
User entered 'No (N)'	System	05 Apr 2021 14:13:36

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-05T09:13:30-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '65d5383f-9f08-40c1-81d1-eb13be7b6fcc'	System	05 Apr 2021 14:13:36
User entered '05 Apr 2021 09:13:30'	System	05 Apr 2021 14:13:36

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-10T10:15:15-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7e15476e-2276-4833-922b-a9737c72c705'	System	10 Apr 2021 15:15:25
User entered 'No (N)'	System	10 Apr 2021 15:15:25

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-10T10:15:19-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7e15476e-2276-4833-922b-a9737c72c705'	System	10 Apr 2021 15:15:25
User entered 'No (N)'	System	10 Apr 2021 15:15:25

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-10T10:15:22-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '7e15476e-2276-4833-922b-a9737c72c705'	System	10 Apr 2021 15:15:25
User entered '10 Apr 2021 10:15:22'	System	10 Apr 2021 15:15:25

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-17T00:55:37-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ea588dfb-36a8-488e-a993-d32cddb75706'	System	17 Apr 2021 05:55:43
User entered 'No (N)'	System	17 Apr 2021 05:55:43

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-17T00:55:40-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ea588dfb-36a8-488e-a993-d32cddb75706'	System	17 Apr 2021 05:55:43
User entered 'No (N)'	System	17 Apr 2021 05:55:43

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-17T00:55:42-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'ea588dfb-36a8-488e-a993-d32cddb75706'	System	17 Apr 2021 05:55:43
User entered '17 Apr 2021 00:55:42'	System	17 Apr 2021 05:55:43

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785614

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-26T22:12:27-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'bd663794-29a8-4f16-b456-719c375c5b74'	System	27 Apr 2021 03:12:41
User entered 'No (N)'	System	27 Apr 2021 03:12:41

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-26T22:12:34-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'bd663794-29a8-4f16-b456-719c375c5b74'	System	27 Apr 2021 03:12:41
User entered 'No (N)'	System	27 Apr 2021 03:12:41

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-04-26T22:12:37-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: 'bd663794-29a8-4f16-b456-719c375c5b74'	System	27 Apr 2021 03:12:41
User entered '26 Apr 2021 22:12:37'	System	27 Apr 2021 03:12:41

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-05-03T15:43:52-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3403f193-0afd-4d3e-8041-5ef657d7ceea'	System	03 May 2021 20:44:07
User entered 'No (N)'	System	03 May 2021 20:44:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-05-03T15:43:58-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3403f193-0afd-4d3e-8041-5ef657d7ceea'	System	03 May 2021 20:44:07
User entered 'No (N)'	System	03 May 2021 20:44:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-05-03T15:44:03-05:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '3403f193-0afd-4d3e-8041-5ef657d7ceea'	System	03 May 2021 20:44:07
User entered '03 May 2021 15:44:03'	System	03 May 2021 20:44:07

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785648

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 08:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785651

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:06:44

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US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785674

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 08:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:06:44

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US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 08:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785767

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 08:06:44

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 08:06:44

FDA-CBER-2022-1614-0785812

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 08:06:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:06:44

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 08:06:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 08:06:44

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:06:44

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US3322341

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:24

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 08:06:44

US3322341
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:05:24
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:06:44
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 08:06:44

US3322341

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:19:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:29-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '87c212c6-63e4-4530-83b3-0962c596b59e'	System	27 Feb 2021 14:08:57
User entered 'Yes (Y)'	System	27 Feb 2021 14:08:57

US3322341

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:24

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:19:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:41-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '87c212c6-63e4-4530-83b3-0962c596b59e'	System	27 Feb 2021 14:08:57
User entered 'No (N)'	System	27 Feb 2021 14:08:57

US3322341

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:24

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:19:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d7922a2fc2559494)', Time: '2021-02-27T08:08:50-06:00', User OID: 'PatientReportedOutcome (US3322341)', ODM File OID: '87c212c6-63e4-4530-83b3-0962c596b59e'	System	27 Feb 2021 14:08:57
User entered '27 Feb 2021 08:08:50'	System	27 Feb 2021 14:08:57

US3322341
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:26:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Dec 2020 22:12:25

US3322341

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:26:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	21 Dec 2020 22:12:25

US3322341
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:26:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	21 Dec 2020 22:12:25

US3322341

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:26:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Dec 2020 22:12:25

US3322341

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
DataPoint Verified.		04 Mar 2021 17:26:38
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Dec 2020 20:37:50

US3322341
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:19
User entered '1'	System	22 Dec 2020 20:37:50

US3322341
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
DataPoint Verified.		04 Mar 2021 17:27:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 20:09:33

US3322341

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
DataPoint Verified.		04 Mar 2021 17:27:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '25 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 20:09:33

US3322341

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
DataPoint Verified.		04 Mar 2021 17:27:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 20:09:33

US3322341

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
DataPoint Verified.		04 Mar 2021 17:27:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 20:09:33

US3322341

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
DataPoint Verified.		04 Mar 2021 17:27:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 20:10:03

US3322341
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User entered '1'	System	26 Jan 2021 20:10:03

US3322341

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:27:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Mar 2021 19:25:43

US3322341
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:27:31
User entered '23 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:25:43

US3322341

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:27:31
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:25:43

US3322341

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:27:31
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:25:43

US3322341

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:27:46
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:25:32

US3322341
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:05:24
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:39:00
User entered '1'	System	02 Mar 2021 19:25:32

US3322341
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:05:24

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:15
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:29:47

US3322341

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:15
User entered '25 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:29:47

US3322341

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:15
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:29:47

US3322341

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:24

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:29:47

US3322341

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:30
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	06 Apr 2021 15:29:40

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:19
User entered '1'	System	06 Apr 2021 15:29:40

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:48:56

US3322341
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '14 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:48:56

US3322341

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:48:56

US3322341
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 20:48:56

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '14 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '15:51'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:51'	System	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '98.2' F	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '65'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '15'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '127'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 20:49:21

US3322341
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '85'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:21

US3322341

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 20:49:21

US3322341

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:33

US3322341

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:24

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:33

US3322341

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:45

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '14 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:45

US3322341

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered '15:41'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:45

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:41'	System	15 Apr 2021 20:49:45

US3322341

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:49:48

US3322341

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:24

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:49:48

US3322341

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:32
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:13

US3322341

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
User entered '14 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:32
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:13

US3322341

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:32
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:13

US3322341
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:05:24
Folder OID

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	13 Apr 2021 20:50:13

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
User closed query 'Per sponsor review: If subject signs informed consent A6, please update this field. If not, then leave this field blank and confirm in response explaining that subject, although unblinded under A6 or later, consent was not taken. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:32:09
Query 'Per sponsor review: If subject signs informed consent A6, please update this field. If not, then leave this field blank and confirm in response explaining that subject, although unblinded under A6 or later, consent was not taken. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:02
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:54
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:54
User entered '14 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:50:54
User opened query 'Per sponsor review: If subject signs informed consent A6, please update this field. If not, then leave this field blank and confirm in response explaining that subject, although unblinded under A6 or later, consent was not taken. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:47:21
User closed query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).		15 Apr 2021 20:47:21
DataPoint Verified.		14 Apr 2021 20:34:43

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'patient has not yet had OLD1' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:45:51
User opened query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:19:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered '0'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Was the participant unblinded?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 15:32:16
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'data is correct ' (Site from System).	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:09
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	15 Apr 2021 20:50:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Participant randomization assignment

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:05:24
Actual Dose 1

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Actual Dose 2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:24

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:34:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:05:23

US3322341
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:05:24
Placebo Only Flag

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 19:05:23

US3322341
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:05:24
Continuing with mRNA-1273

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 19:05:23

US3322341

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:23

US3322341

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
User entered '14 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:23

US3322341

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
User entered '15:41' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:23

US3322341

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:24

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:41'	System	15 Apr 2021 20:51:22
User entered empty.	System	13 Apr 2021 20:50:23

US3322341

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:24

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:13
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:26

US3322341

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:24

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
User entered '14 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:13
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:26

US3322341

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
User entered '15:36' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Apr 2021 20:51:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:13
User entered empty.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 20:50:26

US3322341

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:24

Collection Date and Time (derived)

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:36'	System	15 Apr 2021 20:51:32
User entered empty.	System	13 Apr 2021 20:50:26

US3322341

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:24

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:31
User closed query 'Log line #6 is blank ; please inactivate.' (Site from CRA).		20 Apr 2021 21:20:21
Query 'Log line #6 is blank ; please inactivate.' answered with 'done' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	20 Apr 2021 17:22:40
User opened query 'Log line #6 is blank ; please inactivate.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:29:44
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 18:15:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 16:38:11
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. Thank you' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	25 Jan 2021 20:17:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	25 Jan 2021 20:17:34
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 16:12:56
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:26:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 14:17:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

AEID

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:52:32
Reviewed for Safety.		19 Jan 2021 15:03:01
User entered 'USA-US060-2021-mRNA-1273-P301000007'	System	19 Jan 2021 15:02:57
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 15:02:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haemorrhage, LLT: Postoperative hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Jan 2021 11:51:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Jan 2021 11:51:09
Data point term sent to Coder	System	15 Jan 2021 21:42:05
User entered 'Post-op vaginal hemorrhage'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '13 Jan 2021'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '14 Jan 2021'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Severity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

FDA-CBER-2022-1614-0785968

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User closed query 'PV Query: Please send a hospital discharge summary (including operative note and consulting physician notes) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		09 Feb 2021 16:10:08
Query 'PV Query: Please send a hospital discharge summary (including operative note and consulting physician notes) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'all available information has been sent' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	08 Feb 2021 22:16:28
User opened query 'PV Query: Please send a hospital discharge summary (including operative note and consulting physician notes) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:11:01
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).		02 Feb 2021 17:29:22
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'has been sent' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	01 Feb 2021 19:33:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:22:14
User entered '1'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Generated On: 09 Jun 2021 17:05:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '13 Jan 2021'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		02 Feb 2021 17:32:10
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'the discharge summary was not released upon second request for records, so we feel that it will be unavailable to send, however, we have sent everything we have to the address listed as of 01-feb-2021' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:40:41
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 13:56:24
User entered '14 Jan 2021'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Generated On: 09 Jun 2021 17:05:24

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '1'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User closed query 'PV Query: Please provide causality of Related or Not Related for study procedure.' (Site from Safety).		02 Feb 2021 17:32:13
Query 'PV Query: Please provide causality of Related or Not Related for study procedure.' answered with 'entered' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:40:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	27 Jan 2021 20:46:40
User opened query 'PV Query: Please provide causality of Related or Not Related for study procedure.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:22:57
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	20 Apr 2021 17:22:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 16:35:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:03
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 17:42:35
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:19:28
User closed query 'Per source concomitant medication was noted for this indication. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:19:26
Query 'Per source concomitant medication was noted for this indication. Please confirm with source and update accordingly.' answered with 'updated, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:01:09
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:00:57
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:00:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User opened query 'Per source concomitant medication was noted for this indication. Please confirm with source and update accordingly.' (Site from CRA).		04 Mar 2021 18:33:06
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User closed query 'Per CDM CLR re-query: Thank you for your response. If there are no concomitant procedures in source then please consider removing tick from this field. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:18:12
Query 'Per CDM CLR re-query: Thank you for your response. If there are no concomitant procedures in source then please consider removing tick from this field. Thank you!' answered with 'conprocedure for this AE is number 3 in conprocedures, "SUTURE REINFORCEMENT OF THE VAGINAL CUFF FOR HEMOSTASIS" with indication "adverse event" and was performed on 14JAN2021' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:54:24
User opened query 'Per CDM CLR re-query: Thank you for your response. If there are no concomitant procedures in source then please consider removing tick from this field. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:09:00
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, REPAIR TO RESOLVE BLEEDING. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		15 Mar 2021 07:09:00
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' (Site from Safety).		10 Mar 2021 16:19:42

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Concomitant Procedure

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' answered with 'conprocedure was added, thank you so much for your patience as we reviewed medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:02:51
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:21:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:21:40
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:16:24

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Generated On: 09 Jun 2021 17:05:24

Concomitant Procedure

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, REPAIR TO RESOLVE BLEEDING. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'none in source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:15:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:53:54
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per narrative, REPAIR TO RESOLVE BLEEDING. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		22 Feb 2021 01:25:47
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		12 Feb 2021 14:41:17
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'ok' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:22:51

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Concomitant Procedure

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 10:25:29
User entered '1'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Outcome

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: please clarify start/stop date for concomitant product "unknown dermal filler" ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:33:47
Query 'PV Query: please clarify start/stop date for concomitant product "unknown dermal filler" ' answered with 'not apparent or available in medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	05 Apr 2021 14:59:42
User opened query 'PV Query: please clarify start/stop date for concomitant product "unknown dermal filler" ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:53:28
User closed query 'Per DM CLR: Narrative = INTERNAL SUTURES LOOSENED. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		25 Mar 2021 16:10:55
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, per narrative the medication was only given for INFECTION PROPHYLAXIS. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:10:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Query 'Per DM CLR: Narrative = INTERNAL SUTURES LOOSENED. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'per Sub I, "No, Internal sutures loosened should not be a separate AE. This was part of the patient's description prior to MR being received."' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 19:28:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, per narrative the medication was only given for INFECTION PROPHYLAXIS. Please review and add a Con Medication as appropriate or update action taken.' answered with 'there was no medication for this Ae, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 17:43:59

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Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, per narrative the medication was only given for INFECTION PROPHYLAXIS. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:04:29
User opened query 'Per DM CLR: Narrative = INTERNAL SUTURES LOOSENED. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		24 Mar 2021 04:04:21
User closed query 'Per CDM CLR re-query: Thank you for your answer. If this is still under review then please keep this query open until there is more information and when it is possible to enter Bilateral Salpingectomy under Concomitant Procedure. Thank you!' (Site from DM).		17 Mar 2021 15:16:42
Query 'Per CDM CLR re-query: Thank you for your answer. If this is still under review then please keep this query open until there is more information and when it is possible to enter Bilateral Salpingectomy under Concomitant Procedure. Thank you!' answered with 'it will be added now, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:55:52
User closed query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:31:26
User closed query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open until information is obtained.' (Site from Safety).		15 Mar 2021 14:31:18
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' (Site from Safety).		15 Mar 2021 14:31:12

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Narrative

Audit	User	Time (GMT)
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:10:55
User opened query 'Per CDM CLR re-query: Thank you for your answer. If this is still under review then please keep this query open until there is more information and when it is possible to enter Bilateral Salpingectomy under Concomitant Procedure. Thank you!' (Site from DM).		15 Mar 2021 07:10:47
User closed query 'Per DM CLR: Narrative = BILATERAL SALPINGECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		15 Mar 2021 07:10:47
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Request for medical records has been obtained. LABS on 14JAN2021 0011: Sodium 136, Potassium 3.9, Chloride 103, CO2 24, Anion Gap 9, BUN 17, Creatinine 0.52, Glucose 93, Calcium 9.5, Protein 7.6, Albumin 4.2, A/G ratio 1.2, Alkaline phosphatase 92, AST 20, ALT 13, Total bilirubin 0.5 (normal)14JAN2021 0539: Sodium 137, Potassium 4.0, Chloride 104, CO2 24, Anion Gap 9, BUN 12, Creatinine 0.49, Glucose 97, Calcium 9.1 (Normal) CBC 14JAN2021 0034: WBC 6.6, RBC 4.74, Hgb 13.5, Hct 42.2, MCV 89.0, MCH 28.5, MCHC 32.0, RDW 51.8, MPV 10.7, Plt 196, normal diff. (Normal) CBC 14JAN2021 0536 WBC 5.6, RBC 3.95 (low), Hgb 11.4 (low), Hct 35.7 (low), MCV 90.4, MCH 28.9, MCHC 31.9,RDW 52.3, MPV 10.9, Plt 178, normal diff except eosinophils high at 8.6. 14JAN2021 0111 Estimated GFR greater than=90. 14JAN2021 0539 Estimated GFR greater than =90. normal 14JAN2021 0633 ABO grouping O positive, antibody screen negative. 14JAN2021 0819 COVID 19 qualitative PCR test Not Detected.' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:47:23

Audit	User	Time (GMT)
Query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open until information is obtained.' answered with 'Request for medical records has been obtained. LABS on 14JAN2021 0011: Sodium 136, Potassium 3.9, Chloride 103, CO2 24, Anion Gap 9, BUN 17, Creatinine 0.52, Glucose 93, Calcium 9.5, Protein 7.6, Albumin 4.2, A/G ratio 1.2, Alkaline phosphatase 92, AST 20, ALT 13, Total bilirubin 0.5 (normal)14JAN2021 0539: Sodium 137, Potassium 4.0, Chloride 104, CO2 24, Anion Gap 9, BUN 12, Creatinine 0.49, Glucose 97, Calcium 9.1 (Normal) CBC 14JAN2021 0034: WBC 6.6, RBC 4.74, Hgb 13.5, Hct 42.2, MCV 89.0, MCH 28.5, MCHC 32.0, RDW 51.8, MPV 10.7, Plt 196, normal diff. (Normal) CBC 14JAN2021 0536 WBC 5.6, RBC 3.95 (low), Hgb 11.4 (low), Hct 35.7 (low), MCV 90.4, MCH 28.9, MCHC 31.9,RDW 52.3, MPV 10.9, Plt 178, normal diff except eosinophils high at 8.6. 14JAN2021 0111 Estimated GFR greater than=90. 14JAN2021 0539 Estimated GFR greater than =90. normal 14JAN2021 0633 ABO grouping O positive, antibody screen negative. 14JAN2021 0819 COVID 19 qualitative PCR test Not Detected.' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:47:20

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Audit	User	Time (GMT)
Query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' answered with 'Request for medical records has been obtained. LABS on 14JAN2021 0011: Sodium 136, Potassium 3.9, Chloride 103, CO2 24, Anion Gap 9, BUN 17, Creatinine 0.52, Glucose 93, Calcium 9.5, Protein 7.6, Albumin 4.2, A/G ratio 1.2, Alkaline phosphatase 92, AST 20, ALT 13, Total bilirubin 0.5 (normal)14JAN2021 0539: Sodium 137, Potassium 4.0, Chloride 104, CO2 24, Anion Gap 9, BUN 12, Creatinine 0.49, Glucose 97, Calcium 9.1 (Normal) CBC 14JAN2021 0034: WBC 6.6, RBC 4.74, Hgb 13.5, Hct 42.2, MCV 89.0, MCH 28.5, MCHC 32.0, RDW 51.8, MPV 10.7, Plt 196, normal diff. (Normal) CBC 14JAN2021 0536 WBC 5.6, RBC 3.95 (low), Hgb 11.4 (low), Hct 35.7 (low), MCV 90.4, MCH 28.9, MCHC 31.9,RDW 52.3, MPV 10.9, Plt 178, normal diff except eosinophils high at 8.6. 14JAN2021 0111 Estimated GFR greater than=90. 14JAN2021 0539 Estimated GFR greater than =90. normal 14JAN2021 0633 ABO grouping O positive, antibody screen negative. 14JAN2021 0819 COVID 19 qualitative PCR test Not Detected.' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:47:17
Query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' answered with 'fibroids added to MH' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 22:44:08
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 16:19:34

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Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 16:19:21
Query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained. ' answered with 'information has been entered in conprocedures, thank you' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:04:56
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' answered with 'according to source, not done, as after medical records were reviewed, there were none added' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:03:29
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 18:52:32
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		05 Mar 2021 15:04:16
User closed query 'Per DM CLR: Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		05 Mar 2021 15:04:16
User opened query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:22:13

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:22:13
User opened query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open unti information is obtained.' (Site from Safety).		04 Mar 2021 17:22:06
User closed query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open unti information is obtained.' (Site from Safety).		04 Mar 2021 17:22:06
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:22:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:22:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:21:54
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:21:54

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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:21:48
User closed query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' (Site from Safety).		04 Mar 2021 17:21:48
User closed query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification.' (Site from DM).		04 Mar 2021 15:05:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:17:19
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:17:08
Query 'Per DM CLR: Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'under review' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:16:57
Query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:16:46
Query 'Per DM CLR: Narrative = BILATERAL SALPINGECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'under review' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:16:13

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:16:02
Query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained.' answered with 'under review' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:15:51
Query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification.' answered with 'it is not' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:15:19
User opened query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:29:00
User closed query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).		01 Mar 2021 14:29:00
User opened query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021. Please leave query open until information is obtained.' (Site from Safety).		22 Feb 2021 19:54:22
User opened query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available. Please leave query open unti information is obtained.' (Site from Safety).		22 Feb 2021 19:54:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' (Site from Safety).		22 Feb 2021 19:54:01

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Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:53:19
User opened query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event. Please leave query open until information is obtained.' (Site from Safety).		22 Feb 2021 19:53:14
User closed query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021.' (Site from Safety).		22 Feb 2021 16:19:10
User closed query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' (Site from Safety).		22 Feb 2021 16:18:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		22 Feb 2021 16:18:47
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		22 Feb 2021 16:18:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		22 Feb 2021 16:18:26
User closed query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).		22 Feb 2021 16:18:17

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Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:25:58
User opened query 'Per DM CLR: Narrative = BILATERAL SALPINGECTOMY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		22 Feb 2021 01:25:05
Query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' answered with 'pending review by physician upon obtaining medical records' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:52:02
Query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:59
Query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:52
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:49

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:46
Query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' answered with 'pending review by physician upon obtaining medical records' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 16:51:42
User opened query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:17:19
User closed query 'Per CDM: Please enter conmed data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		19 Feb 2021 15:17:19
User closed query 'Per DM CLR: SAE Narrative = UTERINE FIBROIDS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record thi medical condition in the MH eCRF as appropriate.' (Site from DM).		19 Feb 2021 15:17:06
User opened query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021.' (Site from Safety).		12 Feb 2021 20:41:35
User opened query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' (Site from Safety).		12 Feb 2021 20:41:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Feb 2021 20:41:20

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:41:10
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		12 Feb 2021 20:41:03
User opened query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).		12 Feb 2021 20:40:57
Query 'Per CDM: Please enter conmed data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'ok' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 15:48:29
User closed query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:01:38
User closed query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021' (Site from Safety).		12 Feb 2021 15:01:29
User closed query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' (Site from Safety).		12 Feb 2021 15:01:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Feb 2021 15:01:06

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Folder: Adverse Events
Form: Adverse Events (3)
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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:00:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		12 Feb 2021 15:00:35
User opened query 'Per CDM: Please enter conmed data when it becomes available (or is confirmed to b unavailable). This query will remain open in the meantime. ' (Site from DM).		12 Feb 2021 14:42:50
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' canceled (Site from DM).		12 Feb 2021 14:42:09
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		12 Feb 2021 14:41:53
User closed query 'Per DM CLR: SAE Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Feb 2021 14:41:53
Query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:41

US3322341
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:05:24
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:37
Query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:34
Query 'Per DM CLR: SAE Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'medical records under review by physician, no available data yet to enter' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:30
Query 'Per DM CLR: SAE Narrative = UTERINE FIBROIDS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'medical records under review by physician, no available data yet to enter' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:26
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:22
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:19

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Adverse Events
Form: Adverse Events (3)
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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'medical records under review by physician, no available data yet to enter' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:23:15
User opened query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:11:28
User opened query 'PV Query: Please clarify actual type of surgery and the date of surgery. Narrative reports 13 Jan 2021 and admitted overnight for precautionary measure. Emergency Department notes suggests the subject went to OR the morning of 14 Jan 2021' (Site from Safety).		08 Feb 2021 17:11:20
User opened query 'PV Query: It was noted in Emergency department's notes that a CBC and CMP were ordered, however no results provided. Please provide when available.' (Site from Safety).		08 Feb 2021 17:10:52
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' canceled (Site from DM).		07 Feb 2021 10:25:20
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		07 Feb 2021 10:25:17
User opened query 'Per DM CLR: SAE Narrative = PROPHYLACTIC ANTIBIOTIC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		07 Feb 2021 10:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = UTERINE FIBROIDS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 10:24:56
User closed query 'PV Query: Per medical history, it was reported subject had irregular menstruation. Please confirm if this is menometrorrhagia. If so, please update accordingly.' (Site from Safety).		02 Feb 2021 17:32:18
User closed query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).		02 Feb 2021 17:32:16
Query 'PV Query: Per medical history, it was reported subject had irregular menstruation. Please confirm if this is menometrorrhagia. If so, please update accordingly.' answered with 'yes, it can be, thank you' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:41:32
Query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' answered with 'per attending sub-I, "need to review medical records as patient did not give uterine fibroids as the cause of the irregular menses. Could have been discovered during the procedure. Will need to question patient. "' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	02 Feb 2021 15:41:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:23:52
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		25 Jan 2021 21:23:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		25 Jan 2021 21:23:39

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Folder: Adverse Events
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Generated On: 09 Jun 2021 17:05:24
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Per medical history, it was reported subject had irregular menstruation. Please confirm if this is menometrorrhagia. If so, please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:23:28
User opened query 'PV Query: Please confirm if uterine fibroids should be reported as medical history or separate event.' (Site from Safety).		25 Jan 2021 21:23:13
User entered 'Spoke with patient today at 1351. Patient reported overnight hospital admission to Methodist Sugar Land Hospital from 13JAN2021 through 14JAN2021. Patient had post- op vaginal bleeding from Robotic laparoscopic- assisted Hysterectomy with bilateral salpingectomy on 28DEC2020. Patient had scheduled hysterectomy as treatment for uterine fibroids and menometrorrhagia. Patient was recovering well, when she started experiencing increased vaginal bleeding. After informing her OB/GYN, she was instructed to meet him in the ER for further evaluation. Upon examination, patient was informed that internal sutures loosened and she would have to undergo a repair to resolve bleeding. Patient tolerated repair without incident and was observed overnight as a precautionary measure. No further complications noted. Patient was discharged to home in stable condition with prophylactic antibiotic. Patient is doing well without any complaints. Patient will follow up with her OB/GYN as scheduled. Request for medical records has been obtained.'	Frances Saubon (b) (4) (b) (4)	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:24

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 21:41:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:13:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:13:21
Data point term sent to Coder	System	24 Feb 2021 21:20:53
User entered 'Abdominal pain due to abdominoplasty'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

US3322341
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Severity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User closed query 'Per CDM: Per CCGs p. 51, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:14:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
Query 'Per CDM: Per CCGs p. 51, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'entry error, correct, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:17:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:16:59
User opened query 'Per CDM: Per CCGs p. 51, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:18:19
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4) (b) (4), (b) (6)	24 Mar 2021 22:09:11
DataPoint Verified.		17 Mar 2021 15:30:47
User closed query 'Per source action taken is noted as Not applicable. Please confirm with source and update accordingly' (Site from CRA).		17 Mar 2021 15:30:45
User closed query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 51,Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify' (Site from DM).		10 Mar 2021 17:02:05
Query 'Per source action taken is noted as Not applicable. Please confirm with source and update accordingly' answered with 'updated per newly updated source, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:00:11
Query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 51,Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify' answered with 'updated per newly updated source, thank you!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:00:05
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:59:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4) (b) (4), (b) (6)	09 Mar 2021 21:59:47
DataPoint Verified.		05 Mar 2021 18:49:36
User opened query 'Per source action taken is noted as Not applicable. Please confirm with source and update accordingly' (Site from CRA).		05 Mar 2021 18:49:35
DataPoint Un-verified.		04 Mar 2021 18:52:38
DataPoint Verified.		04 Mar 2021 18:50:49

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 51,Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:18:36
User entered 'None (NONE)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

US3322341
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24
None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:34:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:49
Signature has been broken.	Elisa Moralez (b) (4)	29 Mar 2021 20:43:02
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	29 Mar 2021 20:43:02
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
	(b) (4)	
DataPoint Un-verified.	Elisa Moralez (b) (4)	24 Mar 2021 19:30:19
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4)	24 Mar 2021 19:30:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4)	24 Feb 2021 21:20:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:47
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	29 Mar 2021 20:43:02
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Mar 2021 20:43:02
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:11:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 19:30:26
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 19:30:19
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 19:30:19
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:04:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '1'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

US3322341
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 17:05:24
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:20:45

US3322341

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 21:20:45

US3322341

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:20:45

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 21:22:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 21:22:07
Data point term sent to Coder	System	24 Feb 2021 21:21:55
User entered 'Hypertension'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:21:18

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 21:21:18

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
Severity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '1'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

US3322341
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 17:05:24
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:52:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 21:21:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:05:24

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 21:21:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:31
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:30:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:24:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:28:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:28:16
Data point term sent to Coder	System	05 Oct 2020 15:27:23
User entered 'albuterol'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'asthma'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '90'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'ug (ug)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'as needed (PRN)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:20:15
User closed query 'Per medical records start of Albuterol is noted as UNFeb2005. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:20:12
Query 'Per medical records start of Albuterol is noted as UNFeb2005. Please confirm with source and update accordingly.' answered with 'that is correct, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:05:56
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:05:42
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:05:42
User entered 'UN Feb 2005' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:05:42
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User opened query 'Per medical records start of Albuterol is noted as UNFeb2005. Please confirm with source and update accordingly.' (Site from CRA).		04 Mar 2021 17:41:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Feb 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 15:26:27

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: SUBSTITUTED ALKYLAMINES, PRODUCT: CHLORPHENAMINE MALEATE, PRODUCTSYNONYM: CHLORPHENIRAMINE MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:29:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:29:21
Data point term sent to Coder	System	05 Oct 2020 15:28:25
User entered 'chlorpheniramine maleate'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'seasonal allergies'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '4'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:20:25
User closed query 'Per medical records start date is noted as UNJun2005. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:20:23
Query 'Per medical records start date is noted as UNJun2005. Please confirm with source and update accordingly.' answered with 'that is correct, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:20
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:12
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:12
User entered 'UN Jun 2005' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User opened query 'Per medical records start date is noted as UNJun2005. Please confirm with source and update accordingly.' (Site from CRA).		04 Mar 2021 17:42:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Jun 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:27:33

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 10:24:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 10:24:26
Data point term sent to Coder	System	05 Oct 2020 15:28:27
User entered 'Garden of Life multivitamin'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:29:55
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:44:06
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:43:59
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:08:33
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'general health'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:15
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'UPDATED' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:37:15
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:37:08
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:12:22
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered empty.	Blessing Felix-Okoroji	05 Oct 2020 15:28:24
	(b) (4)	

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:28:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:28:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:30:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:30:29
Data point term sent to Coder	System	05 Oct 2020 15:29:28
User entered 'Biotin'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:00
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:44:26
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:44:18
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:08:56
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'general health'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:21
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:37:45
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:37:37
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:12:33
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2005'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:29:21

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: DIET FORMULATIONS FOR TREATMENT OF OBESITY, PRODUCT: LINOLEIC ACID, PRODUCTSYNONYM: CONJUGATED LINOLEIC ACID CLA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:05:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:05:21
Data point term sent to Coder	System	05 Oct 2020 15:30:30
User entered 'Conjugated linoleic acid (CLA)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'WEIGHT LOSS AID'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:26
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:38:19
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:38:08
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:12:41
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered empty.	Blessing Felix-Okoroji	05 Oct 2020 15:30:07
	(b) (4)	

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 15:48:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 15:48:57
User entered 'No (N)' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:57
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 15:30:07
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:30:07

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: CHROMIUM PICOLINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:01:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:01:20
Data point term sent to Coder	System	05 Oct 2020 15:34:40
User entered 'chromium picolinate'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'weight loss aid'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:30
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:38:42
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:38:29
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:12:48
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:34:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LEVOCARNITINE, PRODUCTSYNONYM: L CARNITINE [LEVOCARNITINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:56:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:56:26
Data point term sent to Coder	System	05 Oct 2020 15:35:43
User entered 'L carnitine'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:12
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:51:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:50:34
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:09:46
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:35
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:06
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:38:52
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:12:57
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:35:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:37:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:37:21
Data point term sent to Coder	System	05 Oct 2020 15:36:44
User entered 'Probiotics'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:19
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:52:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:52:00
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:10:09
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:35
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:40
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:41
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:35
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:13:36
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:36:29

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:38:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:38:26
Data point term sent to Coder	System	05 Oct 2020 15:37:48
User entered 'Vitamin B1'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:24
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:53:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:52:54
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:10:32
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:45
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:58
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:54
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:14:07
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:39:54
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:37:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINAMIDE, PRODUCTSYNONYM: VITAMIN B3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:40:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:40:30
Data point term sent to Coder	System	05 Oct 2020 15:39:52
User entered 'Vitamin B3'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:29
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:57:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:57:15
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:11:47
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:49
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:40:14
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:40:10
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:14:15
User entered 'UNKNOWN' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:51:08
User entered 'OTHER'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:49:48
User entered 'ug (ug)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:40:10
User entered 'UNKNOWN' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:49:48
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:39:16

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:39:16

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:33:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:33:26
Data point term sent to Coder	System	05 Oct 2020 15:40:54
User entered 'testosterone'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:30:35
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:57:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:57:42
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:12:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji	05 Oct 2020 15:40:24
	(b) (4)	

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:54
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:29
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:25
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:14:23
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:25
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji	05 Oct 2020 15:40:24
	(b) (4)	

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:40:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: TONICS, ATC: TONICS, ATC: HERBAL TONICS, OTHER, PRODUCT: MORINGA OLEIFERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:42:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:42:24
Data point term sent to Coder	System	05 Oct 2020 15:41:56
User entered 'Moringa'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:35:07
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:57:55
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:12:31
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:44:59
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:47
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:42
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:14:33
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:42
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:59
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:41:25

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: HERBAL NUTRIENTS, PRODUCT: LINUM USITATISSIMUM SEED OIL, PRODUCTSYNONYM: FLAX SEED OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:44:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:44:21
Data point term sent to Coder	System	05 Oct 2020 15:42:59
User entered 'flax seed oil'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:35:12
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:15
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:13:31
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:45:04
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:58
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:19:09
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:41:58
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:42:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;MAGNESIUM CITRATE, PRODUCTSYNONYM: CALCIUM MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:45:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:45:27
Data point term sent to Coder	System	05 Oct 2020 15:44:01
User entered 'calcium magnesium citrate'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:35:17
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:28
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:13:55
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:45:08
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:22
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:15
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:19:16
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:15
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:43:42

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ALGAE NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 22:04:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 22:04:36
Data point term sent to Coder	System	05 Oct 2020 15:45:03
User entered 'Sea moss'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:35:23
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:41
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:14:15
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:30:23
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 17:37:02
User entered 'UNK' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 17:36:58
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:43:11
User entered 'UNKNONWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:45:13
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:37
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:31
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:27:34
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once daily (QD)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN May 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:50:25
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:44:24

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:10:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:50:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:50:32
User closed query 'Per CDM: Kindly review and update the Medication name to reflect the complete name (generic/trade) of the medication as appropriate. Thankyou.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 15:23:06
Query 'Per CDM: Kindly review and update the Medication name to reflect the complete name (generic/trade) of the medication as appropriate. Thankyou.' answered with 'per source, site has had multiple unsuccessful attempts to obtain medical records with details of IV drip therapy.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	22 Dec 2020 15:46:25
User opened query 'Per CDM: Kindly review and update the Medication name to reflect the complete name (generic/trade) of the medication as appropriate. Thankyou.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:03:02
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).		22 Dec 2020 14:58:41
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' answered with 'Pending medical records, data changes will be reflected once available.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 17:01:09

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:27:42
Data point term sent to Coder	System	07 Dec 2020 21:54:35
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	07 Dec 2020 21:54:05
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'Clarifying with subject, awaiting response. Data will reflect changes when available, thank you' (Site from System).	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 21:54:05
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 11:56:07
Data point term sent to Coder	System	05 Oct 2020 15:46:10
User entered 'IV drip therapy'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:10:46
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 18:15:26
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:59:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:58:56
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:14:42
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:10:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'GENERAL HEALTH'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:10:54
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:30:34
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 17:37:24
User entered 'UNK' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 17:37:20
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:47:25
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:10:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:45:23
Query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:51
User entered 'UNK' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Oct 2020 14:42:46
User opened query 'Per CDM-Dose per administration is recorded as 'UNKNOWN'. Kindly consider to update 'UNK' if dose is unknown in the field 'Dose per administration'. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:27:50
User entered 'UNKNOWN'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'every week (QS)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Intravenous (INTRAVENOUS)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:38
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'UN Mar 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 15:10:30
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:32
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '23 Oct 2020' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 15:10:30
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
DataPoint Verified.		17 Mar 2021 16:11:31
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
User entered '1'	System	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
User entered '1'	System	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:24
User entered '803 (803)'	System	05 Oct 2020 15:45:26

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: PSEUDOEPHEDRINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:00:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:00:31
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:22:25
Data point term sent to Coder	System	09 Mar 2021 22:07:12
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: PSEUDOEPHEDRINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:15:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:15:19
Data point term sent to Coder	System	05 Oct 2020 15:47:13
User entered 'pseudoephedrine HCI'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:23
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:22:21
User closed query 'Per source indication noted as Sinus Headache (exacerbation of seasonal allergies). Kindly update EDC to reflect as noted in source. Thank you.' (Site from CRA).		17 Mar 2021 15:21:01
Query 'Per source indication noted as Sinus Headache (exacerbation of seasonal allergies). Kindly update EDC to reflect as noted in source. Thank you.' answered with 'updated, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:05
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:43
User entered 'SINUS HEADACHE Sinus Headache (Exacerbation of seasonal allergies)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:06:43
User opened query 'Per source indication noted as Sinus Headache (exacerbation of seasonal allergies). Kindly update EDC to reflect as noted in source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:54:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'SINUS HEADACHE'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:19
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '10'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered empty.	Blessing Felix-Okoroji	05 Oct 2020 15:46:39
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'other (OTHER)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:11
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'EVERY 4 HOURS'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:22:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '01 Oct 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
DataPoint Verified.		17 Mar 2021 15:21:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Was this medication taken for solicited event?=No, however PSINUS HEADACHE is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:06:51
Query 'Per DM CLR: Was this medication taken for solicited event?=No, however PSINUS HEADACHE is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' answered with 'entered per source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 20:44:58
User opened query 'Per DM CLR: Was this medication taken for solicited event?=No, however PSINUS HEADACHE is Solicited Events per Protocol and reported in Diary (1-7 days SAR reporting) with corresponding dates. Please verify information and update eCRF accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:15:29
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
User entered empty.	System	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
User entered empty.	System	05 Oct 2020 15:46:39

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:29
User entered empty.	System	05 Oct 2020 15:46:39

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:31
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 20:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 20:44:51
Data point term sent to Coder	System	01 Dec 2020 20:44:40
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 20:44:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:50:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:50:31
Data point term sent to Coder	System	05 Oct 2020 15:49:19
User entered 'Acetaminophen'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:38
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:40
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 18:17:03
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 20:44:26
User entered 'SINUS HEADACHE (exacerbation of seasonal allergies)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 20:44:19
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 13:16:34
User entered 'SINUS HEADACHE'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '500'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:47
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'once (ONCE)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:54
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:22:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:23:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '30 Sep 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:23:04
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:23:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:23:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '30 Sep 2020'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
DataPoint Verified.		17 Mar 2021 15:23:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered empty.	System	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered empty.	System	05 Oct 2020 15:48:38

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:32
User entered empty.	System	05 Oct 2020 15:48:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:18:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:18:57
Data point term sent to Coder	System	12 Jan 2021 18:17:45
User entered 'IBUPROFEN'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

FDA-CBER-2022-1614-0786408

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).		24 Mar 2021 19:56:10
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'the procedure itself did not last 2 days, but the medication did' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:20:26
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:09:20
DataPoint Verified.		17 Mar 2021 15:24:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'HYSTERECTOMY'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:11
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '600'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:24:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'as needed (PRN)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

FDA-CBER-2022-1614-0786414

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:53
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '28 Dec 2020'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:50
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:48
User closed query 'Per source stop date is 29Dec20. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:23:31
Query 'Per source stop date is 29Dec20. Please confirm with source and update accordingly.' answered with 'thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:31
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:26
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:26
User opened query 'Per source stop date is 29Dec20. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:56:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:42
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:47
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:26
User entered '29 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:07:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Jan 2021 18:17:42
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Jan 2021 18:16:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

FDA-CBER-2022-1614-0786420

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
DataPoint Verified.		17 Mar 2021 15:23:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User entered empty.	System	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User entered empty.	System	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:36
User entered empty.	System	12 Jan 2021 18:16:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:30:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:30:58
Data point term sent to Coder	System	12 Jan 2021 18:17:43
User entered 'CODEINE/ACETAMINOPHEN'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:50
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).		24 Mar 2021 19:56:40
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'the medication was taken on 28 and 29 december, that is correct' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:20:54
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:09:33
DataPoint Verified.		17 Mar 2021 15:24:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'HYSTERECTOMY'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:54
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '5/325'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'as needed (PRN)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:42
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:40
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '28 Dec 2020'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:33
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:24:32
User closed query 'Per source stop date is noted as 29Dec20. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:24:26
Query 'Per source stop date is noted as 29Dec20. Please confirm with source and update accordingly.' answered with 'updated, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:09
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:00
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:00
User opened query 'Per source stop date is noted as 29Dec20. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:57:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:24:30
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:00
User entered '29 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:00
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
DataPoint Verified.		17 Mar 2021 15:24:28
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User entered empty.	System	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User entered empty.	System	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:40
User entered empty.	System	12 Jan 2021 18:17:34

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:37:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:37:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Data point term sent to Coder	System	24 Feb 2021 16:06:11
User entered 'Metronidazole'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).		29 Mar 2021 17:07:30
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'PN made on 15-Jan-21, subject stated , metronidazole being prescribed for vaginal bleeding' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	26 Mar 2021 15:11:05
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:04:03
DataPoint Verified.		17 Mar 2021 15:29:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Vaginal Bleeding'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:36
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '500'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:31
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:27
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:26
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:22
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '13 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:31:25
User entered '15 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:31:25
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '14 Feb 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:31:25
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
DataPoint Verified.		17 Mar 2021 15:29:15
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
User entered '3'	System	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
User entered '1'	System	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:45
User entered '804 (804)'	System	24 Feb 2021 16:05:32

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:07:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:07:57
Data point term sent to Coder	System	24 Feb 2021 16:07:14
User entered 'Metroprolol'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'hypertension'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '25'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:46
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:42
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:40
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:55:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 16:06:31

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 16:06:31

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:27:37
Data point term sent to Coder	System	29 Mar 2021 20:43:42
Data point term sent to Coder	System	23 Mar 2021 19:21:28
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:21:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:52
Data point term sent to Coder	System	09 Mar 2021 22:09:14
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:53:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:53:08
Data point term sent to Coder	System	24 Feb 2021 16:07:14
User entered 'Methocarbamol'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 01:46:18
User closed query 'Per source indication was updated Please confirm with source and update accordingly.' (Site from CRA).		31 Mar 2021 01:46:08
User entered 'abdominoplasty and abdominal muscle repair/Abdominal pain due to abdominoplasty' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Mar 2021 20:43:25
Query 'Per source indication was updated. Please confirm with source and update accordingly.' answered with 'thanks' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:21:23
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:21:17
User entered 'ABDOMINOPLASTY AND ABDOMINAL MUSCLE REPAIR' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:21:17
User opened query 'Per source indication was updated. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:53:16
User closed query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		18 Mar 2021 19:53:16
Query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' answered with ' it does not say that in source yet' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 19:29:15
User opened query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:38:16
DataPoint Verified.		17 Mar 2021 15:31:43
User closed query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:31:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:46
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:39
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:39
User entered 'Tummy tuck and Muscle repair' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:39
User opened query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:45:58
Query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' canceled (Site from CRA).		04 Mar 2021 18:30:32
DataPoint Verified.		04 Mar 2021 18:28:20
User opened query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' (Site from CRA).		04 Mar 2021 18:16:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Pain control/Muscle relaxant'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		19 Mar 2021 19:34:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'waiting on update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 19:30:52
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 04:02:12
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '750'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:50:18
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' answered with 'dates updated, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:22
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
User entered '24 Feb 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
DataPoint Verified.		04 Mar 2021 18:28:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User entered '3'	System	24 Feb 2021 16:07:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User entered '1'	System	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:51
User entered '804 (804)'	System	24 Feb 2021 16:07:05

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:43:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:43:57
Data point term sent to Coder	System	17 Mar 2021 20:31:33
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:58:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:58:43
Data point term sent to Coder	System	09 Mar 2021 22:09:14
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:55
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:56:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:56:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Data point term sent to Coder	System	24 Feb 2021 18:35:45
User entered 'Gabapentin'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:50:59
User closed query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		18 Mar 2021 19:50:57
Query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' answered with 'updated' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:16
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:10
User entered 'abdominoplasty and abdominal muscle repair' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:10
User opened query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:38:28
DataPoint Verified.		17 Mar 2021 15:31:38
User closed query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:31:36
Query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' answered with 'Tummy tuck and Muscle repair' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:58
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:55
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:55
User entered 'Tummy tuck and Muscle repair' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:08:55
User opened query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:46:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:30:28
DataPoint Verified.		04 Mar 2021 18:28:18
User opened query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' (Site from CRA).		04 Mar 2021 18:17:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Pain control (Abdominoplasty)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered '100'	Elisa Moralez (b) (4)	24 Feb 2021 18:35:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).		24 Mar 2021 19:56:54
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'date is correct' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:22:07
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:11:12
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '24 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:50:34
Query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'dates updated, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:42
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:10:59
User opened query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).		21 Mar 2021 02:10:41
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).		21 Mar 2021 02:10:33
DataPoint Verified.		04 Mar 2021 18:28:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:32:37
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).		30 Mar 2021 08:31:07
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
User entered '24 Feb 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:08:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
DataPoint Verified.		04 Mar 2021 18:28:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User entered '3'	System	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User entered '1'	System	24 Feb 2021 18:35:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:54
User entered '804 (804)'	System	24 Feb 2021 18:35:00

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:22:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:22:56
Data point term sent to Coder	System	17 Mar 2021 20:31:33
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:59:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:59:50
Data point term sent to Coder	System	09 Mar 2021 22:09:13
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:06:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:06:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Feb 2021 18:35:47
User entered 'Clindamycin'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:51:06
User closed query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		18 Mar 2021 19:51:05
Query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' answered with 'updated' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:47
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:26
User entered 'abdominoplasty and abdominal muscle repair' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:31:26
User opened query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:38:37
DataPoint Verified.		17 Mar 2021 15:31:50
User closed query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:31:29
Query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' answered with 'thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:11
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:05
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:05
User entered 'Tummy tuck and Muscle repair' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:05
User opened query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:46:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:30:23
DataPoint Verified.		04 Mar 2021 18:28:16
User opened query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' (Site from CRA).		04 Mar 2021 18:17:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Abdominoplasty'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '300'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'four times daily (QID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).		24 Mar 2021 19:57:06
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'date is correct' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:22:37
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:11:30
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '24 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:50:45
Query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'updated, thank you!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:51
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
User opened query ' Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:11:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:19:05
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'taken as recovery from the procedure' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 20:38:07
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:31:55
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
User entered '02 Mar 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:07:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
DataPoint Verified.		04 Mar 2021 18:28:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User entered '4'	System	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User entered '1'	System	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:52:58
User entered '804 (804)'	System	24 Feb 2021 18:35:46

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ANTIBIOTICS, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:17:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:17:52
Data point term sent to Coder	System	17 Mar 2021 20:32:33
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:32:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:51:49
Data point term sent to Coder	System	09 Mar 2021 22:10:15
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:09:49

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Data point term sent to Coder	System	24 Feb 2021 18:36:48
User entered 'Ciprofloxacin'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:51:12
User closed query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		18 Mar 2021 19:51:11
Query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' answered with 'updated' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:32:33
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:32:15
User entered 'abdominoplasty and abdominal muscle repair' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 20:32:15
User opened query 'Per source indication updated to abdominoplasty and abdominal muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:38:47
DataPoint Verified.		17 Mar 2021 15:31:25
User closed query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:31:22
Query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' answered with 'thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:25
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:20
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:20
User entered 'Tummy tuck and Muscle repair' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:09:20
User opened query 'Per source indication updated to Tummy tuck and Muscle repair. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 18:46:44

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:30:18
DataPoint Verified.		04 Mar 2021 18:28:13
User opened query 'Please confirm if this medication is for the Tummy Tuck and Muscle repair procedure. If so, please consider updating indication.' (Site from CRA).		04 Mar 2021 18:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Abdominoplasty'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '500'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

FDA-CBER-2022-1614-0786547

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).		25 Mar 2021 17:11:40
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' answered with 'date is correct' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:22:50
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:11:54
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '24 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:11:45
Query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' answered with 'dates updated, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:05
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
User opened query 'Per DM CLR: Please review start/end dates as the duration is unexpected for this Surgical Procedure. Please update start and end dates as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:12:00
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
User entered '02 Mar 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:09:00
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered empty.	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
DataPoint Verified.		04 Mar 2021 18:28:13
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User entered '2'	System	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User entered '1'	System	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:02
User entered '804 (804)'	System	24 Feb 2021 18:36:23

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 20:39:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 20:39:06
Data point term sent to Coder	System	30 Mar 2021 20:38:28
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 20:38:27
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:36:51
Data point term sent to Coder	System	15 Mar 2021 21:53:58
User entered 'Unknown dermal filler'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:19:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'cosmetic, elective' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 20:38:36
User entered 'COSMETIC' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 20:38:27
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:33:52
User entered 'Cosmetic facial injection'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered '1'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'mL (mL)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'un UNK 2021'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered '0'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'un UNK 2021'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:50:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
User entered empty.	System	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
User entered empty.	System	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:24

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:53:07
User entered empty.	System	15 Mar 2021 21:53:41

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:05:24

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:31
DataPoint Verified.		04 Mar 2021 16:43:37
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	11 Jan 2021 18:09:23

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:14:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '28 Dec 2020'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:11:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:14:24
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:56:15
User entered 'Robotic laparoscopic-assisted Hysterectomy, bilateral salpingectomy' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:56:15
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'HYSTERECTOMY'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:11:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:14:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:11:59

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:05:24

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:14:24
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'ELECTIVE'	Frances Saubon (b) (4) (b) (4)	12 Jan 2021 18:11:59

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:01
DataPoint Verified.		17 Mar 2021 16:15:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:08:11

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:15:09
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:59:10
User entered 'Abdominoplasty and abdominal muscle repair' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 18:59:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Tummy tuck and muscle repair'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:08:11

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:01
DataPoint Verified.		17 Mar 2021 16:15:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:08:11

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:05:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:01
DataPoint Verified.		17 Mar 2021 16:15:09
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered 'elective procedure'	Elisa Moralez (b) (4) (b) (4)	24 Feb 2021 16:08:11

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:15:12
User entered '14 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:02:31

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:24

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:15:12
User entered 'Suture reinforcement of the vaginal cuff for hemostasis'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:02:31

US3322341

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:05:24

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:15:12
User entered 'Adverse Event (AE)'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:02:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:15:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 22:02:31

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786600

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786603

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786610

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786615

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786616

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '19/Jan/2021 10:03'	(b) (4) System	19 Jan 2021 15:03:19

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered '1'		19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786625

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:25:51
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
	(b) (4)	
Un-reviewed for Safety.	System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

FDA-CBER-2022-1614-0786638

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:05:24
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '28/Jan/2021 18:05'	System	28 Jan 2021 18:05:27

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:05:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:36:52
User entered '1'		28 Jan 2021 18:05:27

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786645

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

FDA-CBER-2022-1614-0786654

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

FDA-CBER-2022-1614-0786656

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 17:05:24
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '02/Feb/2021 12:37'	(b) (4) System	02 Feb 2021 17:37:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
Reviewed for Safety.		10 Mar 2021 16:21:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:01

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:25:55
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786669

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

FDA-CBER-2022-1614-0786672

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 17:05:24
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
User entered '10/Mar/2021 11:21'	(b) (4) System	10 Mar 2021 16:22:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
Reviewed for Safety.		25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:22:07

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786686

Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

FDA-CBER-2022-1614-0786691

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 17:05:24
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered '15/Mar/2021 08:04'	System	15 Mar 2021 15:04:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
Reviewed for Safety.		25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:05
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:04:51
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'USA-US060-2021-MRNA-1273-P301000007'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Serious

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:21:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Death

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:14
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:24

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	23 Apr 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 01:48:31
User closed query 'please re-verify' (Site from CRA).		09 Apr 2021 01:48:20
Query 'please re-verify' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:05
User entered 'No (N)'	System	08 Apr 2021 21:32:01
Un-reviewed for Safety.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:32:01
User opened query 'please re-verify' (Site from CRA).	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:53
DataPoint Un-verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:23:15
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:22:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:25:55
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

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US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:16:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'No (N)'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:24:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Yes (Y)'	System	19 Jan 2021 15:02:57

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	(b) (4) System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Veronica'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Teresa'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
Un-reviewed for Safety.	System	15 Mar 2021 15:04:51
Signature has been broken.	System	15 Mar 2021 15:04:51
User entered 'Fragoso'	System	15 Mar 2021 15:04:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Becker'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:35
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '6550 Mapleridge Street'	System	19 Jan 2021 15:02:57

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered 'Houston'	System	19 Jan 2021 15:02:57

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:41
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:35:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:09:11
User entered 'TX'	System	15 Mar 2021 15:04:51

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:43
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:03:11
User entered '77081'	System	19 Jan 2021 15:02:57

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 15:15:45
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:03:04
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:05:10
User entered 'US'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 09 Jun 2021 17:05:24
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 13:36:04
User entered '5'	System	15 Mar 2021 15:04:51
User entered '4'	System	10 Mar 2021 16:22:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:03:04
	(b) (4)	
User entered '3'	System	02 Feb 2021 17:37:01
User entered '2'	System	28 Jan 2021 18:05:27
User entered '1'	System	19 Jan 2021 15:03:19

US3322341
Folder: SAE USA-US060-2021-MRNA-1273-P301000007
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 17:05:24
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	31 Mar 2021 23:59:18
User entered '25/Mar/2021 13:36'	System	25 Mar 2021 13:36:04

Folder: SAE USA-US060-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:05:24

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:37:44
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:59:18
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	25 Mar 2021 13:36:04

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